

Facteurs de risque hémorragiques sous anticoagulant en gériatrie (étude SAFIR)

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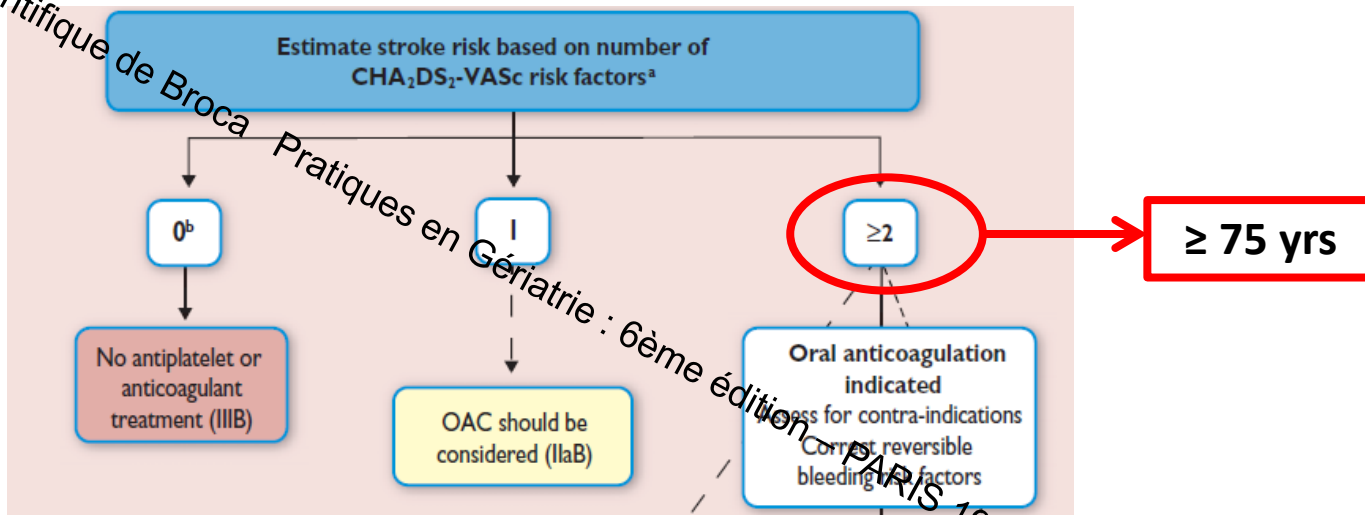


Disclosures

- Bayer, Novartis, Boehringer Ingelheim, Sanofi, BMS, Pfizer, Astra-Zeneca, Servier, Vifor, Boston scientific

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

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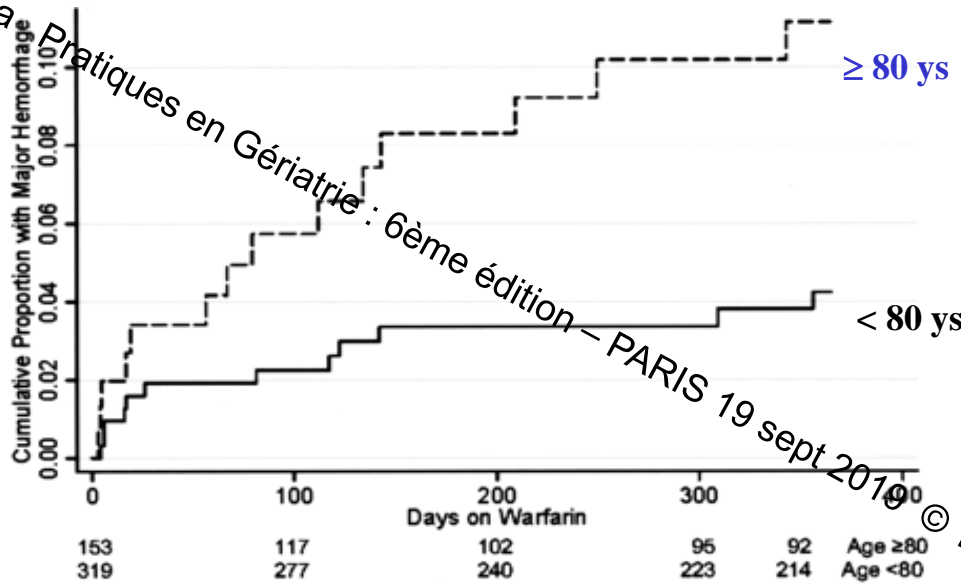


It is recommended that AF patients aged 75 and older with AF receive anticoagulant therapy, Taking into account the hemorrhagic risk

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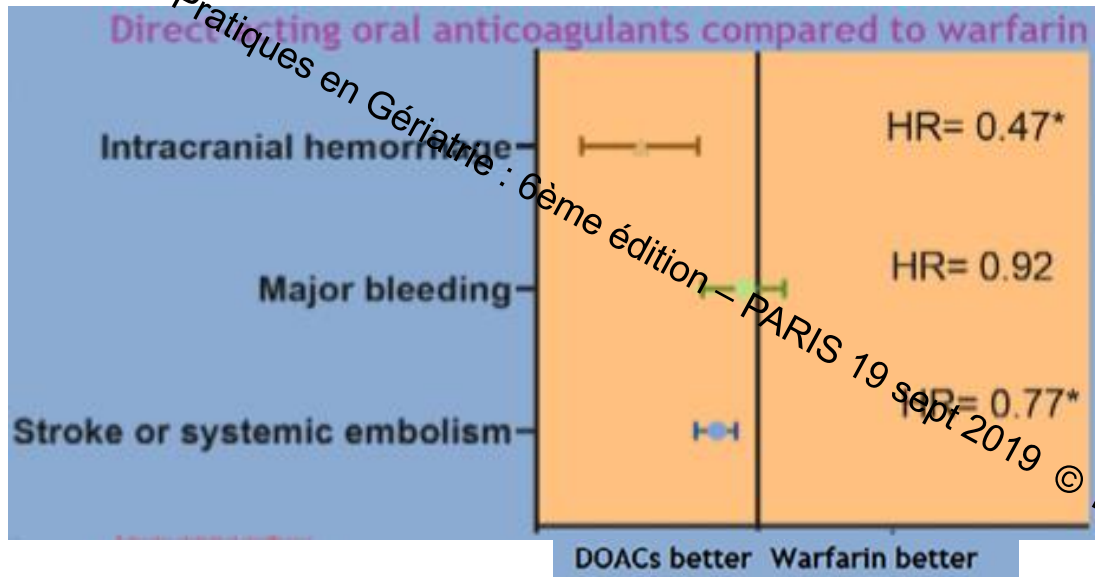
Together with

But bleeding risk increases with aging



Meta-Analysis of Direct-Acting Oral Anticoagulants Compared With Warfarin in Patients >75 Years of Age

Evidence from 28,135 randomized older patients with atrial fibrillation



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Few geriatric patients were included in RCT

- **Geriatric population :**

- > 80 years
- Comorbidities (cognitive disorders, falls, depression, renal dysfunction, malnutrition, anemia...)
- Loss of autonomy
- This population will significantly increase in the next few years

- **Real world data with DOACs in this frail very old population are needed**

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SAFiR-AC



BLEEDING RISK IN ELDERLY SUBJECTS AGED MORE THAN 80 YEARS IN ATRIAL FIBRILLATION TREATED BY RIVAROXABAN ANTICOAGULANT

Principal Investigator : Pr O Hanon (Paris, France)

Funding : supported by an unrestricted grant from Bayer

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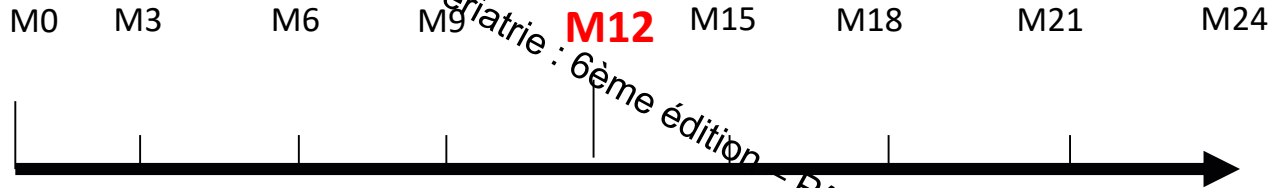
Objective : To assess **bleeding risk** in a French **geriatric population** of **AF subjects**, aged > 80 years treated with Rivaroxaban or VKA

PROSPECTIVE Study

33 geriatrics settings

INCLUSION CRITERIA

> 80 years, Non valvular AF,
Recent initiation of Rivaroxaban (2014-17)
or VKA (2012-15)



- **BASELINE :**
- Clinical data, Treatment, Biology
- HASBLED, HEMORR2HAGES, ATRIA CHADS2, CHA2DS2-VASc
- MMSE, GDS, ADL, IADL, MNA, TUG, Charlson, Morisky

/ 3 months (phone visits)

Mortality,
Bleeding
Hospitalizations
Persistence of Rivaroxaban

Primary Outcome

- **Major bleeding events (ISTH criteria):**

Bleeding associated with

- Death
- Involvement of a critical anatomical site (intracranial, spinal, ocular, pericardial, retroperitoneal, articular or intramuscular with compartment)
- Drop in hemoglobin concentration ≥ 2 g/dL
- Transfusion of ≥ 2 units of whole blood or red blood cells

Rocket AF NEJM 2011

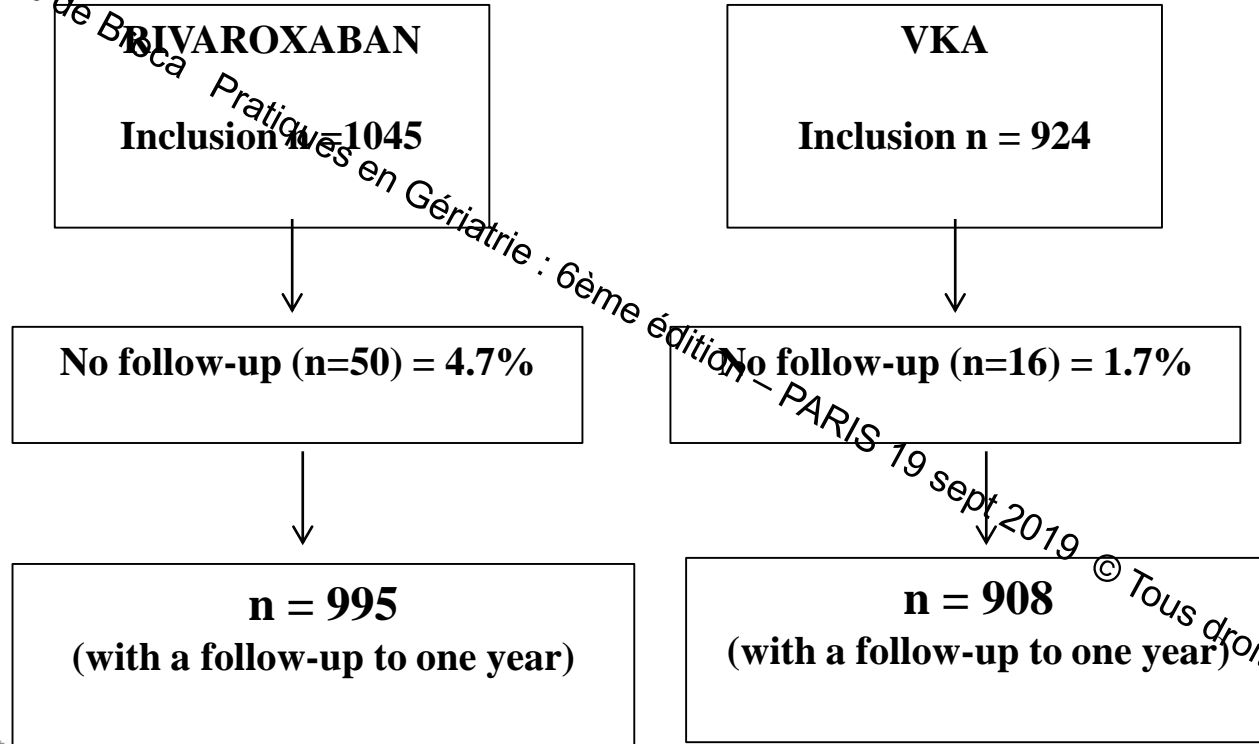
- Major bleeding events **were adjudicated by an independent committee**

Together with

Secondary Outcome variables

- Number and time to
 - **death**
 - **stroke or systemic embolism**
- Determinants of hemorrhagic events (risk score)
- Treatment discontinuation, treatment adherence

POPULATION



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Statistical analysis

- Kaplan-Meier curves were drawn for clinical events over time in the two groups.
- Cox proportional hazard models were used to calculate hazard ratio (HR) and 95% CI for the incidence of clinical events in the two groups

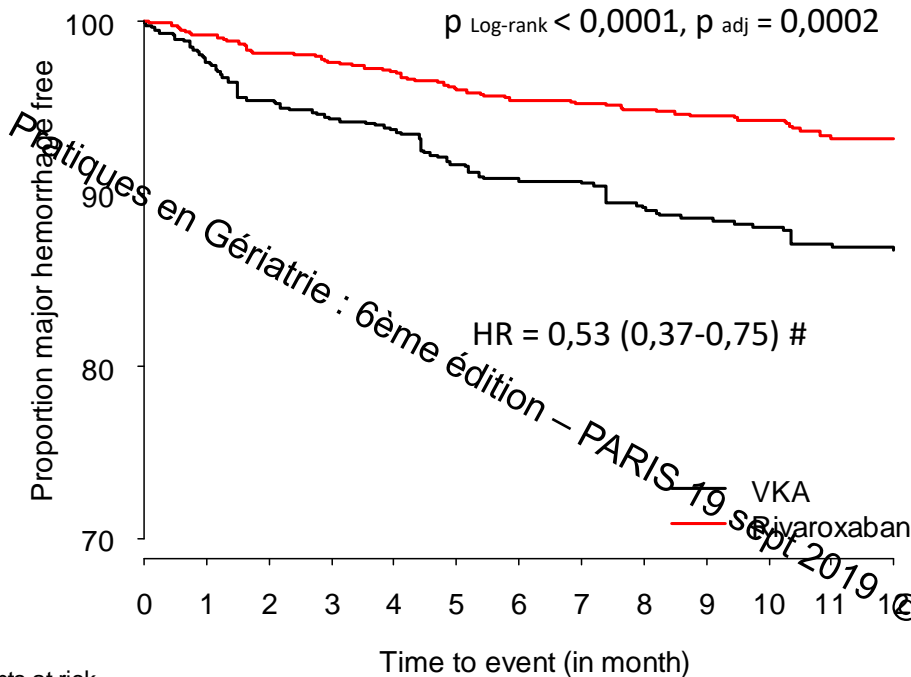
Model 1 : *adjusted for age, sex, eGFR and Charlson index (n= 22 variables)*

Model 2 : *adjusted for age, sex, eGFR, Charlson index, falls, malnutrition antiplatelet agents, PPI, SRI, amiodarone intake (n= 28 variables)*

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RESULTS

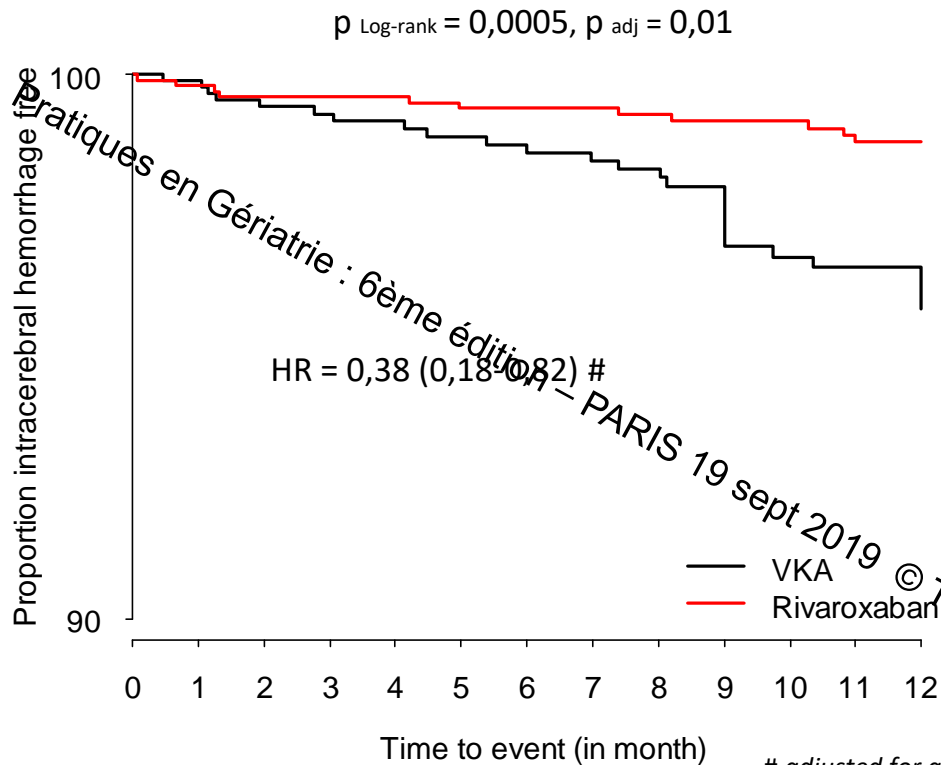
Major bleedings



Patients at risk	0	1	2	3	4	5	6	7	8	9	10	11	12
Rivaroxaban	994	994	919	860	799	755	658	658	533	533	520	520	520
VKA	908	868	808	755	658	658	533	533	533	533	501	501	501

adjusted for age, sex, eGFR and Charlson index

Intracerebral hemorrhages



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adjusted for age, sex, eGFR and Charlson index

Conclusions

- **SAFIR** : First specific study in **Geriatric population**
- Prospective Design
- **In this very old and frail patients:**
Higher risk of bleeding compared to younger population

- **DOAC compared to VKA**
 - **Less major bleeding**
 - **Less intracerebral bleeding**

- **DOAC (Rivaroxaban) can be used in geriatric populations**