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Effectiveness and safety of rivaroxaban 15mg compared with vitamin k antagonists in very elderly patients with atrial fibrillation: a matched cohort in the French nationwide claims database (SNIIRAM)*

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Introduction

- In clinical trials, direct oral anticoagulants (DOAC) had better benefit-risk than vitamin K antagonists (VKA) for non-valvular atrial fibrillation (NVAF)
- No data in the old elderly (≥85 years of age) from RCT
- Is the use of low-dose rivaroxaban in patients ≥85 appropriate?

Objective

- To compare 1-year risk of
  - Effectiveness endpoints: stroke and systemic embolism (SSE), acute coronary syndrome, death
  - Safety endpoint: bleeding (major bleeding, clinically relevant bleeding)

  in new users of rivaroxaban 15mg or VKA ≥ 85 years for NVAF

Design

- Cohort study in the 66 Million persons French nationwide claims and hospitalisation database (SNDS[1])
  - New users of rivaroxaban, dabigatran, or VKA in 2013-2014
  - With diagnosis of NVAF[2]
  - With 3-year history and 1-year follow-up in database

[1]*Système National des Données de Santé*
[2]Long-term disease registration, hospitalisation or procedure for atrial fibrillation without rheumatic valve disease or valve replacement, and nor other probable indication

Outcomes *(on treatment)*

- Hospital admission (primary diagnosis) for:
  - Stroke and systemic embolism (SSE)
  - Major bleeding* (MB)
  - Clinically relevant bleeding*
  - Acute coronary syndrome
- Death (all-cause)
- Composite criterion (SSE, MB, or death)

* Primary, linked or associated diagnosis for haemorrhagic stroke

Statistical analysis

- Matched analysis on gender, age, date of the first anticoagulant dispensing, and high-dimensional propensity score (hdPS)
- 1-year cumulative incidence of outcomes using Kaplan-Meier estimate
- Comparison of risk using Cox proportional hazard risk model (death, composite) or Fine and Gray model (other single outcomes)

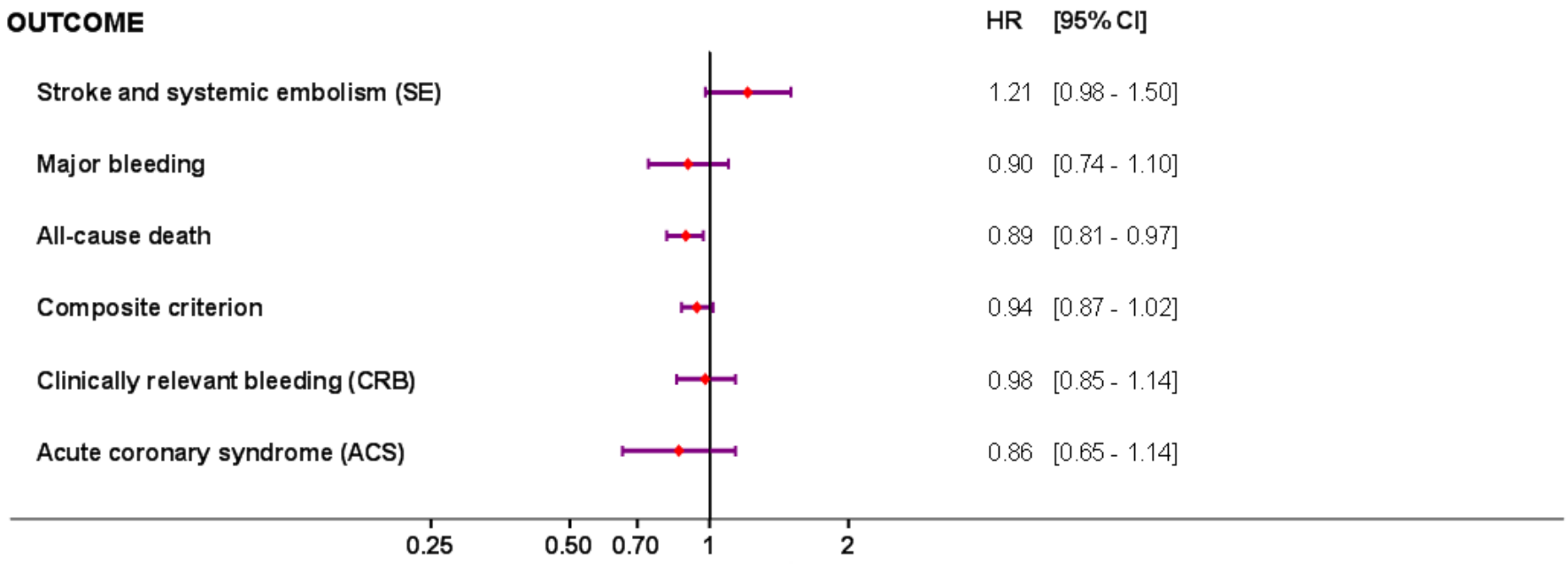
Patients characteristics in matched populations

	Rivaroxaban 15mg ≥ 85 years n = 7,762	VKA ≥ 85 years n = 7,774
Male	36.8%	36.6%
Age, mean (± SD)	88.5 (2.9)	88.5 (2.9)
Risk factors		
- Hypertension	51.2%	50.2%
- Diabetes mellitus	17.0%	16.9%
- Vascular disease history	16.0%	17.0%
- Congestive heart failure	31.4%	31.2%
- Stroke or TIA history	12.1%	11.0%
- Abnormal renal function	8.3%	9.2%
- Abnormal liver function	1.0%	1.0%
- CHA_2DS_2-VASc score ≥ 2	100.0%	100.0%
- HAS-BLED score ≥ 3	43.4%	45.0%

One-year cumulative incidence of outcomes

	Rivaroxaban 15mg ≥ 85 years n = 7,762	VKA ≥ 85 years n = 7,774
Stroke and systemic embolism (SSE), %	3.1	2.5
Major bleeding (MB), %	3.1	3.4
Clinically relevant bleeding, %	5.6	5.7
Death, %	15.1	17.2
Composite criterion (SE, MB, death), %	19.2	20.5
Acute coronary syndrome, %	1.4	1.7

Effectiveness and safety: rivaroxaban 15mg *vs* VKA
(matched analysis, ≥85 years patients)



Discussion / Conclusion

In patients ≥85 treated for NVAF with rivaroxaban 15mg or VKA:

- There was no difference for non-fatal outcomes including bleeding
- There was a lower risk of death with rivaroxaban 15mg

- Rivaroxaban can be used safely even in the very elderly (not included in RCT)