

SHORT-TERM RISK OF BLEEDING DURING HEPARIN BRIDGING AT INITIATION OF VITAMIN K ANTAGONIST THERAPY IN MORE THAN 90,000 PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION MANAGED IN OUTPATIENT CARE

KIM BOUILLON¹, MARION BERTRAND¹, LOTFI BOUDALI¹, PIERRE DUCIMETIÈRE², ROSEMARY DRAY-SPIRA¹, MAHMOUD ZUREIK¹

1. French National Agency for Medicines and Health Products Safety (ANSM), Saint-Denis, France; 2. Paris Sud-XI University, Villejuif, France

BACKGROUND

- Few studies have investigated bridging risks during vitamin K antagonist (VKA) initiation, in particular in outpatient settings.
- There is an overall consensus in favour of a bridging the rapy prior to urgent cardioversion
 in patients with life-threatening hemodynamic instability caused by new-onset NVAF.
- The recommendation in guidelines is less clear for those with stable NVAF who do not require rapid anticoagulation
- In real-life conditions, a bridging regimen is commonly used in those with a low stroke risk.¹⁻⁴ This practice is not supported by evidence.

OBJECTIVES

To assess the safety and effectiveness of a bridging regimen during the initiation of VKA therapy in NVAF patients managed in outpatient care.

METHODS

Sources

- French health insurance claims databases (SNIIRAM)
- French hospital discharge database (PMSI)

Study population

Patients starting a VKA (warfarin, fluindione, or acenocoumarol) dispensed from a community pharmacy between January 2010 and November 2014 for NVAF, aged 18 years or over.

Comparison groups

- Bridging therapy: SC bridging agent (LMWH, fondaparinux, UFH) + VKA
- Reference group: VKA only

Outcomes (ICD-10 codes)

- Bleeding: intracranial, gastrointestinal, other
- Arterial thromboembolism: ischemic stroke, sustemic embolism (IS/SE)

Statistical analysis

- Multivariate analysis: adjusted hazard ratios (HR) with 95% confidence intervals (CI) were estimated using Cox models
- Duration of follow-up: first and two following months of anticoagulation
- Covariates: sex, age, social deprivation index, type of VKA therapy, type of VKA prescribers, comorbidities (CHA2DS2-VASc and HAS-BLED scores etc.), concomitant medications.

RESULTS

Study population: 90,826 individuals (mean age of 72 years, 50% women), 30% with bridging therapy.

Figure 1. Multivariable adjusted association of bridging therapy with bleeding and IS/SE risks

Event	Not bridged	Bridged N (%)	Hazard ratio	HR [95% CI]
Bleeding				
1 month FU	191 (0.30)	127 (0.47)		1.60 [1.28-2.01]
2-3 months FU	162 (0.32)	69 (0.29)	-	0.93 [0.70-1.23]
Stroke/systemic em	bolism			
1 month FU	107 (0.17)	44 (0.16)	-	1.00 [0.70-1.42]
2-3 months FU	84 (0.16)	38 (0.16)		1.11 [0.76-1.64]
		0.0	0.5 1.0 1.5 2.0 2.5	

Figure 2. Multivariable adjusted association of bridging therapy with one-month bleeding risk according to sex

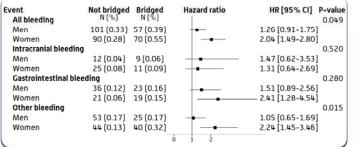
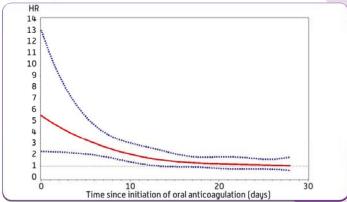


Figure 3. Effect of bridging therapy on bleeding with time estimated by a cubic spline function



CONCLUSION

At VKA initiation for NVAF managed in ambulatory settings, bridging therapy is associated with a higher risk for bleeding and a similar risk for arterial thromboembolism as compared with no bridging therapy.

REFERENCES

- 1. Kim et al. J Thromb Haemost 2015.
- Billett et al. J Thromb Thrombolysis 2010.
- 3. Smoyer-Tomic et al. Am J Cardiovasc Drugs Drugs Devices Interv 2012.
- 4. Gerber et al. BMC Cardiovasc Disord 2012.

Declaration of Interest: Authors have nothing to disclose.

Contact details: Kim Bouillon, MD, PhD, kim.bouillon@ansm.sante.fr



