P6246

‘Truly low-risk’ patients with newly diagnosed non-valvular atrial fibrillation at risk of stroke: 1-year outcomes from the GARFIELD-AF Registry

Jean-Pierre Bassand[1], Samuel Z Goldhaber[2], A John Camm[3], Alexander GG Turpie[4], Frank Misselwitz[5], Seil Oh[6], Martin Van Eickels[5], Giancarlo Agnelli[7], Pekka Raatikainen[8], Ajay K Kakkar[9], for the GARFIELD-AF Investigators

[1]Department of Cardiology, University Hospital Jean-Minjoz, Besançon, France; [2]Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, USA; [3]St George’s University of London, London, UK; [4]Department of Medicine, Hamilton Health Sciences, Hamilton, Ontario, Canada; [5]Bayer HealthCare Pharmaceuticals, Berlin, Germany; [6]Seoul National University Hospital, Seoul, South Korea; [7]University of Perugia, Perugia, Italy; [8]University of Tampere, Tampere, Finland; [9]Thrombosis Research Institute, London, UK

BACKGROUND

- Patients with non-valvular atrial fibrillation (AF) and a CHA_2DS_2-VASc risk score of 0 are considered by current European Society of Cardiology guidelines to be at low risk of stroke[1]
- CHA_2DS_2-VASc is considered better than $CHADS_2$ for identification of truly low-risk patients[1]
- Low-risk patients should not receive antithrombotic therapy according to the guidelines, whereas all patients with a risk score of ≥1 should receive anticoagulant therapy[1]

PURPOSE

- To study outcomes in truly low-risk patients (CHA_2DS_2-VASc=0) compared with patients with a $CHADS_2$ score of 0 and patients with a risk score of ≥1 on either scale in the Global Anticoagulant Registry in the FIELD-Atrial Fibrillation (GARFIELD-AF)

METHODS

- GARFIELD-AF is an ongoing, international, observational registry of consecutively recruited patients aged ≥18 years with newly diagnosed (≤6 weeks’ duration) non-valvular AF and ≥1 additional investigator-determined stroke risk factor(s)[2]
- Patients in this study are recruited into successive cohorts; at the time of this analysis, $CHADS_2$ and CHA_2DS_2-VASc scores were available for 12,185 and 12,174 out of 12,448 patients (cohorts 1 and 2), respectively
- Stroke risk factors were not prespecified in the study protocol, nor were they limited to those included in the $CHADS_2$ and CHA_2DS_2-VASc risk scores
- In the current analysis of cohorts 1 and 2, patient demographics, including $CHADS_2$ and CHA_2DS_2-VASc stroke risk scores, were recorded and clinical outcomes reported after 1 year of follow-up
- Clinical outcomes were the incidences of all-cause death, stroke/systemic embolism and major bleeding
- Unadjusted hazard ratios for each clinical outcome were estimated using a Cox proportional hazards model

RESULTS

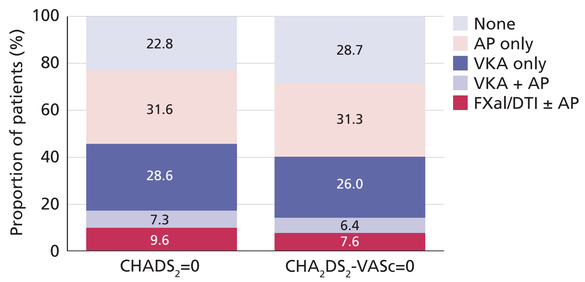
- A total of 12,448 prospective patients with AF were enrolled at 739 sites in 30 countries between March 2010 and June 2013
- $CHADS_2$ and CHA_2DS_2-VASc scores were missing for 2.1% (n=263) and 2.2% (n=274) of patients, respectively
- A total of 6.6% and 3.6% of patients had a $CHADS_2$ and CHA_2DS_2-VASc score of 0, respectively; these patients were younger than those in the overall population (Table 1)
- Approximately 75% of low-risk patients ($CHADS_2$ and/or CHA_2DS_2-VASc score of 0) received anticoagulants and/or antiplatelet therapy, irrespective of which score was considered; approximately 26–29% received a vitamin K antagonist only and 31–32% received antiplatelet monotherapy (Figure 1)

Table 1. *Patient baseline characteristics according to risk scores*

	All patients (N=12,448)	$CHADS_2$=0 (n=807/12,185)	CHA_2DS_2-VASc=0 (n=440/12,174)
Age, mean (SD)	70.0 (11.5)	58.6 (11.5)	52.3 (9.8)
Women, %	43.7	34.3	35.2*
Medical history, %			
Congestive cardiac failure	20.2	0	0
Hypertension	77.8	0	0
Coronary artery disease	19.8	11.5	3.9
Diabetes mellitus	22.0	0	0
Peripheral artery disease	7.0	3.6	0
Systemic embolism	0.6	0.1	0
Bleeding	2.9	2.1	2.5
Chronic kidney disease (II–V)#	34.1	15.0	11.6
Risk score, mean (SD)			
$CHADS_2$	1.9 (1.1)	0	0
CHA_2DS_2-VASc	3.3 (1.6)	0.7 (0.9)	0
HAS-BLED	1.4 (0.9)	0.8 (0.7)	0.4 (0.5)

*Female patients with no other risk factors were considered to have a CHA_2DS_2-VASc score of 0.
#Patients with unknown chronic kidney disease status were removed from the denominator.
SD, standard deviation.

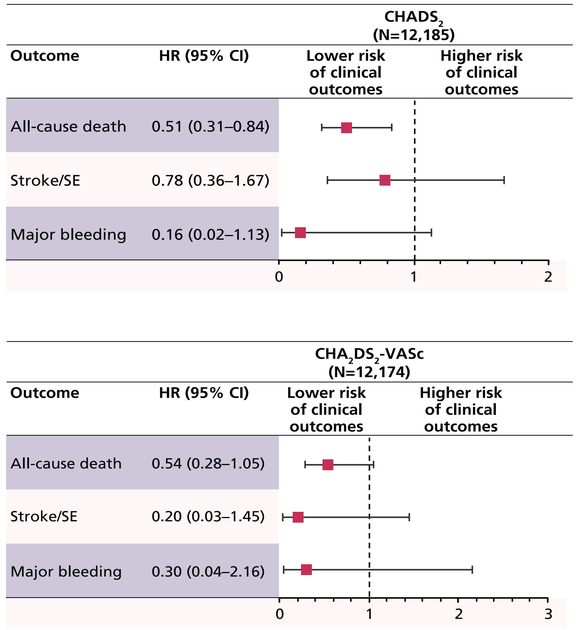
Figure 1. *Antithrombotic therapy initiated at atrial fibrillation diagnosis in low-risk atrial fibrillation patients (risk score=0)*



AP, antiplatelet; DTI, direct thrombin inhibitor; FXaI, Factor Xa inhibitor; VKA, vitamin K antagonist.

- Patients with a $CHADS_2$ or CHA_2DS_2-VASc score of 0 had a lower incidence of all clinical outcomes compared with those with risk scores ≥1 (Table 2); however, the wide confidence intervals for the hazard ratios of stroke/systemic embolism and major bleeding suggest that the comparisons for these outcomes should be interpreted with caution (Figure 2)

Figure 2. *Relative risk of clinical outcomes for low-risk patients ($CHADS_2$ or CHA_2DS_2-VASc=0) compared with patients with risk scores ≥1. Hazard ratios were estimated using a Cox proportional hazards model*



CI, confidence interval; HR, hazard ratio; SE, systemic embolism.

- Although rates of mortality and bleeding were similar in patients with a $CHADS_2$ score of 0 compared with those with a CHA_2DS_2-VASc score of 0, the rate of stroke/systemic embolism was approximately four times greater; however, patient numbers were small (Table 2)

Table 2. *Unadjusted outcomes in patients with atrial fibrillation according to risk scores*

Event rates, n (%)	$CHADS_2$ score (N=12,185)		CHA_2DS_2-VASc score (N=12,174)	
	0 (n=807)	1–6 (n=11,378)	0 (n=440)	1–9 (n=11,734)
All-cause death	16 (2.0)	441 (3.9)	9 (2.0)	447 (3.8)
Stroke/systemic embolism	7 (0.9)	126 (1.1)	1 (0.2)	132 (1.1)
Major bleeding	1 (0.1)	89 (0.8)	1 (0.2)	89 (0.8)

P6246 presented at the 36th Annual Congress of the European Society of Cardiology (ESC), Barcelona, Spain; 30 August–3 September, 2014

CONCLUSIONS

- A minority of patients with non-valvular AF observed in the GARFIELD-AF Registry were classified as low risk by $CHADS_2$ or CHA_2DS_2-VASc score
- Most of the low-risk patients received antithrombotic therapy, and many received anticoagulation against current guideline recommendations[1]
- Low-risk patients tended to have fewer adverse clinical outcomes, including a substantially lower risk of all-cause death, than patients with a $CHADS_2$ or CHA_2DS_2-VASc score ≥1
- No definitive conclusion regarding the respective predictive values of $CHADS_2$ and CHA_2DS_2-VASc can be drawn from these data because of the limited number of patients classified as low risk

Note: 10 patients were excluded from this analysis after abstract submission because of improper consent; as a result, the numbers of patients presented in this poster differ slightly from those in the submitted abstract.

DECLARATION OF INTEREST

The GARFIELD-AF Registry is supported by an unrestricted research grant from Bayer Pharma AG.
J-PB: consultancy fees or honoraria from AstraZeneca.
SZG: research support from Daiichi and EKOS; consultancy for Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi, Eisai, Janssen, Merck, Pfizer, Portola and Sanofi-Aventis.
AJC: research support from Bayer HealthCare, Sanofi, Boehringer Ingelheim, Pfizer and Bristol-Myers Squibb; consultancy for Bayer HealthCare, Sanofi, Boehringer Ingelheim, Pfizer, Bristol-Myers Squibb, Eisai and Daiichi Sankyo.
AGGT: consultancy for Bayer, J&J, Astellas, Merck, Sanofi-Aventis, Takeda and Portola; and on speakers’ bureaus for Bayer, Bristol-Myers Squibb, Pfizer, Boehringer Ingelheim, J&J, GlaxoSmithKline and Sanofi-Aventis.
FM and MvE: employees of Bayer HealthCare.
SO: advisory board for St Jude Medical International; consultant for Bayer, Bristol-Myers Squibb, Boehringer Ingelheim and Sanofi-Aventis.
GA: honoraria from Bayer HealthCare.
PR: research support from St Jude Medical International and Biosense Webster; consultant for Stereotaxis and Meda Pharmaceuticals; honoraria from Bayer, Cardiome, Pfizer, Bristol-Myers Squibb and Boehringer Ingelheim; ownership interest for Orion Pharma.
AKK: research support from Bayer HealthCare, Sanofi-Aventis, Boehringer Ingelheim, Pfizer, Bristol-Myers Squibb, Eisai and Pfizer; consultancy for Bayer HealthCare, Sanofi-Aventis, Boehringer Ingelheim, Pfizer, Bristol-Myers Squibb, Eisai and Daiichi Sankyo; honoraria from Bayer HealthCare, Sanofi-Aventis, Boehringer Ingelheim, Pfizer, Bristol-Myers Squibb, Eisai and GlaxoSmithKline; and Scientific Advisory Board membership for Bayer HealthCare, Sanofi-Aventis, Boehringer Ingelheim, Pfizer, Bristol-Myers Squibb, Eisai and Daiichi Sankyo.

ACKNOWLEDGEMENTS

We thank the physicians, nurses and patients involved in the GARFIELD-AF Registry.

REFERENCES

1. Camm AJ *et al. Eur Heart J* 2012;33:2719–2747.
2. Kakkar AK *et al. Am Heart J* 2012;163:13–19.