Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation: Baseline Characteristics of the first 10,000 Patients in GLORIA-AF Phase II

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Conflict of Interest Statement

I have received honoraria for presentations as well as research grants from Boehringer Ingelheim, Bayer Healthcare, Pfizer, BMS, GSK and Actelion.
Background

• Atrial fibrillation (AF) confers a major risk factor for cardio-embolic stroke
• Availability of novel oral anticoagulants (NOACs) augments the treatment arsenal to expand beyond vitamin K antagonists (VKAs, e.g., warfarin)
• In clinical trials, NOACs have been shown to be comparable or superior to VKAs in reducing stroke occurrence and systemic emboli, with a lower risk of intracranial haemorrhage
Objective and Design of GLORIA-AF

Objective:
To characterize the newly diagnosed non-valvular AF (NVAF) patient population at risk for stroke and to study patterns, predictors and outcomes of different antithrombotic treatment regimes for stroke prevention in clinical practice.

Design:
• Prospective, global, observational study program of up to 56,000 patients with newly diagnosed NVAF run in 3 phases
• Consecutive enrollment of newly diagnosed (≤ 3 months) NVAF patients with ≥ 1 additional risk factor for stroke (CHA2DS2-VASc ≥ 1)
• Up to 2200 AF care setting sites in ~50 countries globally
## Design of GLORIA-AF

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional analysis</td>
<td>Cross-sectional, cohort, case-control analyses</td>
<td>Cross-sectional and comparative analyses</td>
</tr>
</tbody>
</table>

### Status:
- **Phase I**: Ended Jan 2013
- **Phase II**: Currently ongoing (Asia, LatAm, Africa/Middle East)
- **Phase III**: Currently ongoing (North America, Europe)

### Before the approval of dabigatran etexilate
- Baseline Visit
  - 3M
  - 6M
  - 1YR
  - 2YR

### After the approval of dabigatran etexilate
- Baseline Visit
  - 3M
  - 6M
  - 1YR
  - 2YR
  - 3YR

### When baseline characteristics of patients receiving dabigatran and VKA are comparable
- Baseline Visit
  - 3M
  - 6M
  - 1YR
  - 2YR

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GLORIA-AF Phase II – Interim Analysis

Overall 10,675 patients included in Phase II Interim Analysis (enrolled from Nov 2011 to Feb 2014)

Care Setting (Patient %):
Specialist Offices: 33.4%; University Hospitals: 30.8%; Community Hospitals 12.6%; Primary Care 11.4%; Other 11.7%

‘Other’ includes: Outpatient centers; Anticoagulation clinics and other)
Types and Categorization of AF – All Regions

**Types of AF**
- Paroxysmal: 54.5% (n = 10,675)
- Persistent: 34.9% (n = 10,675)
- Permanent: 10.6% (n = 10,675)

**Categorization of AF**
- Symptomatic: 31.4% (n = 10,675)
- Minimally symptomatic: 41.7% (n = 10,675)
- Asymptomatic: 26.8% (n = 10,675)
Antithrombotic Treatment at Baseline – All Regions

Total N = 10,675

 Patients (%)  
<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VKA</td>
<td>3449</td>
<td>32.3%</td>
</tr>
<tr>
<td>Dabi</td>
<td>3439</td>
<td>32.2%</td>
</tr>
<tr>
<td>Riva</td>
<td>1282</td>
<td>12%</td>
</tr>
<tr>
<td>Apix</td>
<td>369</td>
<td>3.5%</td>
</tr>
<tr>
<td>ASA</td>
<td>1225</td>
<td>11.5%</td>
</tr>
<tr>
<td>AP other than ASA</td>
<td>90</td>
<td>0.8%</td>
</tr>
<tr>
<td>None</td>
<td>814</td>
<td>7.6%</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

AP, antiplatelet; ASA, acetylsalicylic acid.; VKA, vitamin K antagonist
### Patient Demographics and Medical History – All Regions

<table>
<thead>
<tr>
<th>Medical History</th>
<th>Total (N = 10675)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR), years</td>
<td>71.0 (64.0, 78.0)</td>
</tr>
<tr>
<td>BMI, median (IQR), kg/m²</td>
<td>27.80 (24.70, 31.80)</td>
</tr>
<tr>
<td>Previous stroke, n (%)</td>
<td>999 (9.4)</td>
</tr>
<tr>
<td>Myocardial infarction, n (%)</td>
<td>1116 (10.5)</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>2195 (20.6)</td>
</tr>
<tr>
<td>Congestive heart failure, n (%)</td>
<td>2530 (23.7)</td>
</tr>
<tr>
<td>History of hypertension, n (%)</td>
<td>7993 (74.9)</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>2454 (23.0)</td>
</tr>
<tr>
<td><strong>CHADS₂ score class</strong>, n (%)</td>
<td></td>
</tr>
<tr>
<td>Low (score = 0)</td>
<td>896 (8.4)</td>
</tr>
<tr>
<td>Moderate (score = 1)</td>
<td>3694 (34.6)</td>
</tr>
<tr>
<td>High (score ≥ 2)</td>
<td>6081 (57.0)</td>
</tr>
<tr>
<td><strong>CHA₂DS₂-VASc score class</strong>, n (%)</td>
<td></td>
</tr>
<tr>
<td>Moderate (score = 1)</td>
<td>1551 (14.5)</td>
</tr>
<tr>
<td>High (score ≥ 2)</td>
<td>9123 (85.5)</td>
</tr>
</tbody>
</table>

BMI, body mass index; IQR, interquartile range.; *According to eligibility criteria, patients had to have a CHA₂DS₂-VASc score ≥ 1 to be eligible for the study.
CHA$_2$DS$_2$-VASc score missing for one patient.

‘Other’ includes antiplatelets other than ASA and combination of oral anticoagulants.
Antithrombotic Treatment at Baseline – By Region

- Europe (n = 4703)
  - Dabi: 38.8%
  - VKA: 10.7%
  - Riva: 2.9%
  - Apixaban: 4.1%
  - ASA: 2.9%
  - Antiplatelets other than ASA: 6.6%
  - None: 7.6%
  - Other: 0.1%

- North America (n = 3415)
  - Dabi: 25%
  - VKA: 26.1%
  - Riva: 20.5%
  - Apixaban: 7.6%
  - ASA: 13.5%
  - Antiplatelets other than ASA: 6.6%
  - None: 0.1%
  - Other: 0.6%

- Asia (n = 1957)
  - Dabi: 23.7%
  - VKA: 16.9%
  - Riva: 31.9%
  - Apixaban: 5.9%
  - ASA: 9.9%
  - Antiplatelets other than ASA: 2.4%
  - None: 0.3%
  - Other: 0.4%

- Latin America (n = 476)
  - Dabi: 46%
  - VKA: 29%
  - Riva: 1.5%
  - Apixaban: 1.6%
  - ASA: 0.4%
  - Antiplatelets other than ASA: 2.4%
  - None: 0.4%
  - Other: 0.8%

- Africa/Middle East (n = 124)
  - Dabi: 61.3%
  - VKA: 16.1%
  - Riva: 16.1%
  - Apixaban: 3.2%
  - ASA: 1.6%
  - Antiplatelets other than ASA: 0.8%
  - None: 0.8%
  - Other: 2.4%

‘Other’ includes combination of oral anticoagulants.
Conclusions

• Large interim analysis of baseline data from GLORIA-AF Phase II shows regional differences in treatment patterns of AF management for stroke prevention

• VKAs still widely used despite increasing use of NOACs in clinical practice

• In some regions (eg. NA and EU), there is increasing uptake of NOACs and preference over VKA

• Despite high stroke risk, high proportions of patients remain undertreated with ASA only, or receive no treatment; this is most pronounced in Asia but also prevalent in North America
Acknowledgements

Scientific Steering Committee
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