Abstract: P1257

ETNA-AF Europe: First 1-year follow-up snapshot analysis of more than 7,500 AF patients treated with edoxaban in routine clinical practice

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On behalf: ETNA-AF-Europe investigators

Topic(s):
Oral Anticoagulation

Citation:

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Daiichi Sankyo Europe GmbH, Munich, Germany

Introduction: Edoxaban has been approved for stroke prevention in patients with atrial fibrillation based on its comparable efficacy and superior safety compared to warfarin in the pivotal ENGAGE AF-TIMI 48 trial. ETNA-AF Europe (NCT02944019) was initiated in agreement with the EMA to evaluate benefits and risks of edoxaban treatment in unselected patients in routine clinical practice.

Methods: 13,980 patients from across 825 hospital and office-based physicians from 10 European countries (Austria, Belgium, Germany, Ireland, Italy, The Netherlands, Portugal, Spain, Switzerland and United Kingdom) were enrolled, and will be followed-up for 4 years. This snapshot analysis includes baseline and first outcome data of 7,672 patients (56.3% of all enrolled patients) that have completed their first 1-year follow-up visit (mean follow-up: 343.5 days).

Results: The average age of patients was 73.4 years, the mean weight was 81.9 kg (Table 1). Frequent comorbidities include hypertension (77.2%), valvular heart disease (17.4%), congestive heart failure (5.8%) and history of myocardial infarction (4.2%). Patients receiving the 30 mg dose (22.9%) were older, had a lower creatinine clearance and had a higher risk for both stroke and bleeding as compared to those on the 60 mg dose (77.1%). Overall, the incidence of clinical events was low: all-cause mortality: 3.56%/y, major bleeding 0.95%/y, intracranial haemorrhage 0.28%/y, any stroke or systemic embolic events 0.88%/y. Conclusions: We found low bleeding and stroke rates in 7,672 unselected, mainly elderly AF patients treated with edoxaban in routine clinical practice. These findings were consistent across edoxaban doses and reinforce the effectiveness and safety of NOACs such as edoxaban in routine clinical care in Europe.

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>All patients [7,672]</th>
<th>Edoxaban 60 mg [5,916 (77.1%)]</th>
<th>Edoxaban 30 mg [1,756 (22.9%)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [years] mean (SD)</td>
<td>73.4 (9.26)</td>
<td>71.8 (8.98)</td>
<td>79.1 (7.81)</td>
</tr>
</tbody>
</table>
### Abstract

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### Authors

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### Methods

13,980 patients from across 825 hospital and office-based physicians from 10 European countries (Austria, Belgium, Germany, Ireland, Italy, The Netherlands, Portugal, Spain, Switzerland and United Kingdom) were enrolled, and will be followed-up for 4 years. This snapshot analysis includes baseline and first outcome data of 7,672 patients (56.3% of all enrolled patients) that have completed their first 1-year follow-up visit (mean follow-up: 343.5 days).

### Results

The average age of patients was 73.4 years, the mean weight was 81.9 kg (Table 1). Frequent comorbidities include hypertension (77.2%), valvular heart disease (17.4%), congestive heart failure (5.8%) and history of myocardial infarction (4.2%). Patients receiving the 30 mg dose (22.9%) were older, had a lower creatinine clearance and had a higher risk for both stroke and bleeding as compared to those on the 60 mg dose (77.1%). Overall, the incidence of clinical events was low: all-cause mortality: 3.56%/y, major bleeding 0.95%/y, intracranial haemorrhage 0.28%/y, any stroke or systemic embolic events 0.88%/y.

### Conclusions

We found low bleeding and stroke rates in 7,672 unselected, mainly elderly AF patients treated with edoxaban in routine clinical practice. These findings were consistent across edoxaban doses and reinforce the effectiveness and safety of NOACs such as edoxaban in routine clinical care in Europe.

### Table 1: Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>All patients</th>
<th>Edoxaban 60 mg</th>
<th>Edoxaban 30 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body weight [kg] mean (SD)</strong></td>
<td>81.9 (17.33)</td>
<td>84.1 (16.80)</td>
<td>74.3 (16.93)</td>
</tr>
<tr>
<td><strong>CrCl (CG) [mL/min] mean (SD)</strong></td>
<td>75.0 (30.29)</td>
<td>82.5 (29.14)</td>
<td>51.2 (19.75)</td>
</tr>
<tr>
<td><strong>CHA2DS2-VASc mean (SD)</strong></td>
<td>3.1 (1.38)</td>
<td>2.9 (1.34)</td>
<td>3.8 (1.28)</td>
</tr>
<tr>
<td><strong>HAS-BLED mean (SD)</strong></td>
<td>2.5 (1.10)</td>
<td>2.4 (1.07)</td>
<td>2.9 (1.08)</td>
</tr>
<tr>
<td><strong>First occurrence of all-cause mortality (n, %/year)</strong></td>
<td>257 (3.56%)</td>
<td>129 (2.31%)</td>
<td>128 (7.90%)</td>
</tr>
<tr>
<td><strong>First occurrence of intracranial haemorrhage (n, %/year)</strong></td>
<td>20 (0.28%)</td>
<td>16 (0.29%)</td>
<td>4 (0.25%)</td>
</tr>
<tr>
<td><strong>First occurrence of major bleeding (n, %/year)</strong></td>
<td>68 (0.95%)</td>
<td>49 (0.88%)</td>
<td>19 (1.18%)</td>
</tr>
<tr>
<td><strong>First occurrence of stroke/SEE (n, %/year)</strong></td>
<td>63 (0.88%)</td>
<td>45 (0.81%)</td>
<td>18 (1.11%)</td>
</tr>
</tbody>
</table>

CG, Cockcroft-Gault; CrCl, creatinine clearance; SD, standard deviation; SEE, systemic embolic events