



Science For A Better Life

## Clinical Study Synopsis

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<b>Title</b>	<b>TRE</b> atment Pattern of <b>NOACs</b> (non-vitamin K oral anticoagulants) in Outpatient Users in Colombian <b>Databases – TREND Colombia</b>
<b>Keywords</b>	Direct Oral Anticoagulants (DOACs), Atrial Fibrillation, Drug Utilization
<b>Rationale and background</b>	Non-vitamin K antagonist oral anticoagulants (NOACs) have several advantages over vitamin K antagonists such as warfarin, including use of fixed dosing with no need for international normalized ratio monitoring, and fewer drug-drug interactions. Data on the patterns of use of NOACs in SPAF patients in routine care in Colombia are lacking. Such data, however, are important in order to study their use in the management of patients with non-valvular atrial fibrillation (NVAF) and whether they are being prescribed in accordance with the drug labelling information.
<b>Research question and objectives</b>	<p>This population-based descriptive study aimed to characterize first-time users of three NOACs (rivaroxaban, dabigatran and apixaban) in patients with NVAF in Colombia, and to assess the patterns of drug utilization in these patients in routine general practice.</p> <p><b>The primary objectives were to:</b></p> <ul style="list-style-type: none"> <li>• provide a detailed description of SPAF patients who are prescribed a NOAC (rivaroxaban, dabigatran and apixaban) for the first time use in an outpatient setting</li> <li>• assess the pattern of outpatient use of NOACs in SPAF patients</li> </ul> <p><b>The secondary objective was to:</b></p> <ul style="list-style-type: none"> <li>• determine time-trends in the characteristics of first-time use of rivaroxaban, dabigatran and apixaban in outpatient SPAF patients</li> </ul>
<b>Study Design</b>	This was a population-based study designed to describe patterns of first-time NOAC use in patients with NVAF in Colombia.
<b>Setting</b>	The study was carried out in a primary care setting in Colombia, South America. The study period was from 01 JUL 2009 to 31 JUN 2017 (the latest date of data collection).
<b>Subjects and Study Size, including dropouts</b>	All patients aged $\geq 18$ years with a diagnosis of NVAF and with at least 1 year of enrollment with their primary care physician (PCP) in the Audifarma S.A database and with 1 year since their first recorded health contact r were eligible for inclusion. Three mutually exclusive cohorts of first-time users of a NOAC (rivaroxaban, apixaban or dabigatran) with the date of first prescription the NOAC (index drug) being the index date, and followed all patients for at least 1 year.
<b>Variables and Data</b>	<b>Patient characteristics:</b> demographics, comorbidities, co-

<b>sources</b>	<p>medications (including prior anticoagulant use – naïve/non-naïve status), and healthcare use</p> <p><b>Index NOAC characteristics:</b> dose, dose posology, duration of use</p> <p><b>Data source:</b> Audifarma S.A outpatient primary care database, the main drug dispensing company within the Health System of Colombia</p>
<b>Results</b>	<p>10,528 patients with NVAF were identified as first-time users of a NOAC during the study period. The incidence rate of patients with NVAF who were started on apixaban or rivaroxaban increased steadily over the study period, whereas for dabigatran, the rate declined after a peak in 2013.</p> <p>The sex distribution of patients was broadly similar between NOAC cohorts with males accounting for more than half: apixaban 56.0%, dabigatran 54.9% and rivaroxaban 59.0%. The mean age was also similar across cohorts: apixaban 78.5 years, dabigatran 76.5 years and rivaroxaban 76.0 years. The apixaban cohort had the highest percentage of anticoagulant naïve patients (70.5%) compared with dabigatran (64.7%) and rivaroxaban (65.8%).</p> <p>Near a half of patients were still prescribed their index NOAC at 6 months (apixaban 44.6%, dabigatran 51.3% and rivaroxaban 52.7%). Among patients starting on apixaban, only 38% received a daily dose of 10mg and just over half (53.5%) received a daily dose of 5 mg, and just over at third (33.3%) had a first episode of continuous apixaban use of <math>\geq 180</math> days. Among patients starting on dabigatran, 30.9% patients were received a daily dose of 300mg and a half (49.5%) received a daily dose of 220 mg, while 18.9% received a daily dose of either 110 mg or 150 mg. Approximately half of patients starting on dabigatran (44.0%) had a first episode of continuous use that lasted more than 180 days while 27.2% had a first episode of continuous use that lasted for at least a year. Among patients starting on rivaroxaban, a total daily dose of 20 mg was the most frequent prescribed (56.9%), followed by a daily of 15 mg (37.4%). A little under half (42.7%) had a first episode of continuous use that lasted more than 180 days</p>
<b>Discussion</b>	<p>The increasing use of NOACs in patients with NVAF in Colombia likely reflects the growing confidence in NOACs among PCPs in Colombia. The characteristics of these patients are in line with those seen in comparable European and American cohorts.</p>
<b>Marketing Authorisation Holder(s)</b>	Bayer AG
<b>Names and affiliations of</b>	<b>Investigators:</b> <span style="background-color: black; color: black;">[REDACTED]</span>

principal investigators	<p><b>Co-investigators:</b></p> <ul style="list-style-type: none"> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> </ul> <p><b>I</b></p> <ul style="list-style-type: none"> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> <li>[REDACTED]</li> </ul>
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