Boehringer Ingelheim

Clinical Study Synopsis for Public Disclosure

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The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

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A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country..

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's Policy on Transparency and Publication of Clinical Study Data**.

1. ABSTRACT

Name of company: Boehringer Ingelheim			
Name of finished medicinal product: Prazaxa			
Name of active ingredient: **Dabigatran exexilate**		Dabigatran etexilate	
Report date: 7 July 2017	**Study number:** 1160.279	**Version/Revision:** Version 1	**Version/Revision date:** Not applicable
Title of study:	Treatment patterns of newly initiated oral anticoagulants on Japanese non-valvular atrial fibrillation patients using a Japanese claims database		
Keywords:	Non-valvular atrial fibrillation, dabigatran, warfarin, claims data analysis, propensity score		
Rationale and background:	Real-world data about the characteristics of patients with NVAF initiating an OAC in Japan has been scarce to date. The purpose of this study is to describe the characteristics of such patients in the MDV database.		
Research question and objectives:	1. To understand the treatment patterns of OACs and baseline patient characteristics of Japanese NVAF patients 2. To determine whether warfarin and dabigatran new user group can be balanced using propensity score matching using pre-specified baseline covariates 3. As an exploratory analysis, to assess mean duration of on-therapy follow-up time in database		
Study design:	A retrospective, observational study using health insurance claims data		
Setting:	MDV clinical database between April 2010 and June 2016 was used.		
Subjects and study size, including dropouts:	Inclusion criteria 1. >18 year-old with confirmed diagnosis of NVAF (ICD 10 code I48) 2. New starters of dabigatran, warfarin, apixaban, rivaroxaban, and edoxaban 3. No prescription of other OACs for12 months prior to the index date, defined as the first prescription of OACs (the period is defined as baseline period) 4. Has an index date between 14th of March 2011 to 30 June 2016 Exclusion criteria 1. Having less than 12 months of enrolment prior to the index date 2. Dialysis or kidney transplant recipients in baseline period 3. Having atrial flutter, valvular AF, mechanical valve placement, rheumatic AF, mitral valve prolapse/regurge/stenosis in baseline		

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	period 4. Having record of deep vein thrombosis or pulmonary embolism < 6 months before AF diagnosis in baseline period
Variables and data sources:	The patient was included in the study has a prescription claim of dabigatran, warfarin, apixaban, or edoxaban between 14th of March 2011 to 30th of June 2016.
Results:	Among the patients diagnosed as NVAF between April 2010 and June 2016, 48,696 patients were prescribed dabigatran, warfarin, apixaban, edoxaban, or rivaroxaban as the first OACs. Among them, the number of eligible patients for those prescribed dabigatran, warfarin, apixaban, rivaroxaban, or edoxaban as the first OAC were 4,943, 12,497, 11,415, 8,767, or 2,272, respectively. Some baseline characteristics such as age distribution, history of hospitalization, some AF risk factor scores, distribution of year of initiating treatment, and some concomitant medication were different among the treatment groups. After propensity score matching based on matching ratio of 1:1, using caliper factor of 0.10, it was confirmed that the distribution of propensity score was similar between the patients prescribed dabigatran and warfarin. The number of matching patients after the matching was 4,421 for both treatment groups. There was no background factor with standardized difference at more than 0.1.
Discussion:	For the eligible patients prescribed dabigatran and warfarin, more than 4,000 patients were obtained after the propensity matching with matching ratio of 1:1, using caliper factor of 0.10. Regarding the number of patients and standardized difference for each baseline factor, the matching ratio of 1:1 is likely to be best for the matching.
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