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			
Report date: 23 February 2017	**Study number:** 1160.254	**Version/Revision:** 1.0	**Version/Revision date:** NA
Title of study:	Comparison of the length of stay in patients hospitalized and initiated with dabigatran or warfarin for a concomitant Non-Valvular Atrial Fibrillation in real-world Japanese therapeutic practice (SHORT-J)		
Keywords:	Non-valvular atrial fibrillation, dabigatran, warfarin, claims data analysis, propensity score		
Rationale and background:	In patient hospitalized with non-valvular atrial fibrillation (NVAF), either dabigatran or warfarin could be initiated. However, warfarin requires a precise dose adjustment for several days to reach an effective International Normalized Ratio (INR). On the other hand, dabigatran is rapidly effective and does not require a dose adjustment, so that we hypothesize that dabigatran treatment strategy could contribute to shorten the length of stay (LoS) from initiation of oral anticoagulant treatment to hospital discharge compared with warfarin treatment strategy.		
Research question and objectives:	The primary objective of this study is to compare the LoS of patients hospitalized and subsequently treated with dabigatran or warfarin for a NVAF in a real-world Japanese therapeutic practice in patients with NVAF. The further objective of this study is to compare the LoS of patients hospitalized with 1) acute ischemic stroke, and 2) due to NVAF.		
Study design:	This is an observational cohort study based on existing data. We will conduct matched propensity score comparison of LoS in patients hospitalized for any reason and initiated with dabigatran or warfarin for a concomitant NVAF in real-world Japanese clinical practice		
Subjects and study size, including dropouts:	Over 800 patients data of each treatment group		
Variables and data sources:	Variables for the analysis was extracted by ICD-10 code for diagnosis information, anatomical therapeutic chemical (ATC) code for prescription information and diagnostic procedure combination (DPC) data for other relevant clinical information. Claims and DPC data were provided by Medical Data Vision Co., Ltd. (MDV).		
Results:	By applying the inclusion and exclusion criteria, the number of patients qualifying for this study was N=4,313 (dabigatran only N= 899, warfarin		

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	only N=3,414). The largest possible matching ratio was 1:3. After 1:3 matching, the number of patients were N=3,036 (dabigatran only N=759, warfarin only N=2,277 (with replacement)). The Average Treatment Effect on the Treated (ATET) of LoS from oral anticoagulant initiation to hospital discharge was -2.5 days (dabigatran - warfarin). The tendency of patients prescribed dabigatran having shorter LoS was present in all analysis scenarios including the sensitivity analyses.		
Discussion:	Regardless of consideration for the baseline period, the causal effect of dabigatran was estimated to shorten LoS. This coincides with the results of prior studies conducted in Japan. This was a real-world claims data study that provides more substantial support for former evidence.		
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