Evaluating Physician Knowledge of Risks and Safe Use of Rivaroxaban

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BACKGROUND

- Rivaroxaban is a non–vitamin K oral anticoagulant with several indications, including the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (i.e., stroke prevention in atrial fibrillation [SPAF]) and the treatment and secondary prevention of deep vein thrombosis (DVT).
- Rivaroxaban was approved in Europe for both SPAF and DVT in 2011.
- As part of a safety risk management plan revision, a Prescriber Guide (PG) and Patient Alert Card (PAC) were developed and distributed in Europe to provide education and increase awareness and understanding about the initiation of rivaroxaban and potential bleeding risk associated with its use.

OBJECTIVE

- To measure whether prescribers received the PG and evaluate their knowledge of key safety messages for the indications of interest.

DISCLOSURES

B. Calingaert, K. Davis, K. Nelson, D. Wolin, and L. Zografos are full-time employees of RTI Health Solutions, which received funding from Bayer AG to conduct this study. E. Andrews is a contract employee for RTI Health Solutions. The contract between RTI Health Solutions and the sponsor includes independent publication rights. RTI conducts work for government, public, and private organisations, including pharmaceutical companies. Y. Lenz, K. Suzart-Woischnik, C. Tarenz, and A. Horvat-Broecker are full-time employees of Bayer Pharma AG, the funder of this study.

METHODS

Study Design

Overview

- This study involved 3 assessments (waves) with physicians across 4 countries: France, Germany, Spain, and the United Kingdom.
- Physicians who had prescribed rivaroxaban in the past 6 months were recruited from a web panel to complete a web-based survey on their knowledge of key safety information for rivaroxaban.
- Data collection occurred from September to November 2014 for wave 1, from March to June 2017 for wave 2, and from January to February 2020 for wave 3.
- The information in this poster focuses primarily on the third wave of the physician surveys.
- Figure 1 provides an overview of the study activities.

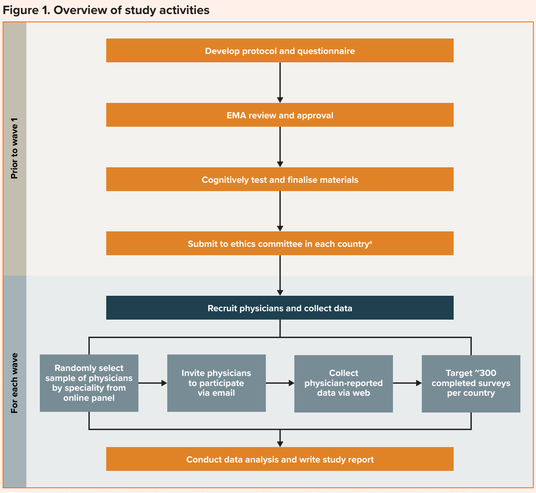
Survey Design and Administration

- The wave 3 questionnaire consisted of 27 questions divided into the following categories: (1) physician and practice characteristics, (2) physician prescribing practices, (3) physician knowledge, (4) sources of information about rivaroxaban, (5) ratings of those sources, and (6) experiences with information contained in the PAC.
- The questionnaire was developed using best practices for instrument development and was tested through cognitive interviews with physicians in each country prior to wave 1.
- Physicians were not able to go back to previous questions, thus prohibiting them from changing their answers based on subsequent questions.

Analysis

- Data analyses were descriptive and focused on summarizing the questionnaire responses by country and overall.
- The results for knowledge questions were reviewed individually by country and overall to assess the effectiveness of the educational material and identify any knowledge gaps. Additionally, knowledge questions were stratified by several other variables (e.g., physician specialty, whether physicians were responsible for initiating or converting treatment vs. maintenance treatment only, and whether they reported receiving the prescriber guide) to try to identify factors associated with physician knowledge level.

Figure 1. Overview of study activities



[a] The questionnaire was submitted to ethics committees as part of the protocol for the overall study, which also included a patient survey component.

RESULTS

Demographics and Experience

- Between 1,224 and 1,297 physicians participated in each assessment, with response rates varying from 5% to 9%. For each wave, there was a fairly even distribution of physicians across the study countries, with approximately 300 respondents per country.
- Waves 2 and 3 included a mix of new participants and physicians who participated in prior waves. The numbers of new participants in wave 3 were as follows: 229 (65% of respondents) in France, 208 (66%) in Germany, 129 (42%) in Spain, and 214 (67%) in the United Kingdom.
- Approximately three-quarters (75%) of physicians were male.
- The most frequent specialties represented in the survey population were general medicine (36%), cardiology (18%), internal medicine (15%), and neurology (9%).
- Most physicians (91%) reported practicing medicine for more than 10 years, and 25% reported practicing medicine for more than 25 years.
- More than half of physicians (55%) reported their practice setting as general practice; 51% reported practicing in a hospital-based clinic.

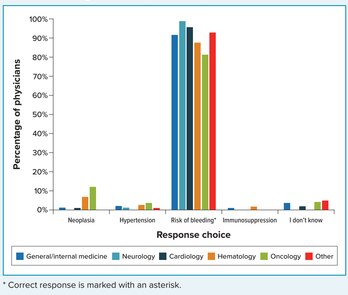
Receipt and Review of Prescriber Guide

- Most physicians reported that they received the prescriber guide (57%). Other common sources of information reported included the summary of product characteristics (58%) and a briefing from a company representative (56%).
- Of the physicians who reported receiving the prescriber guide, 80% rated it as either very helpful or extremely helpful.

Knowledge Questions

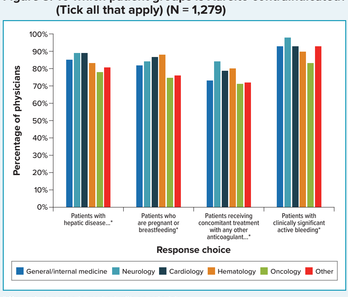
- Knowledge was remarkably similar across the 3 assessments, with slight improvement over time for several knowledge questions. The remainder of this section refers to the overall third wave results:
  - Knowledge was high (93% correct) on the overall risk of bleeding (Figure 2) and on a series of questions about contraindicated populations (74%-92%; Figure 3) and populations at increased risk of serious side effects (68%-93%; Figure 4).
  - A lower percentage of physicians (68%) were aware that rivaroxaban 15 mg and 20 mg should be taken with food (Figure 5). While almost all physicians (93%) knew that routine coagulation monitoring is not required, knowledge was lower (62% and 75%) for 2 questions on specific situations that do require international normalized ratio (INR) monitoring (Figure 6). The lowest percentages of correct responses were on questions related to converting to parenteral anticoagulants and converting to/from vitamin K antagonist (VKA) (35%-75%).
  - Neurologists, cardiologists, and haematologists showed higher levels of knowledge than other specialists. Physicians responsible for initiating or converting treatment had higher knowledge than those responsible only for maintenance treatment. Physicians who reported receiving the PG had higher knowledge than those who did not.

Figure 2. What is the most important risk associated with taking Xarelto? (N = 1,280)



* Correct response is marked with an asterisk.

Figure 3. To which patient groups is Xarelto contraindicated? (Tick all that apply) (N = 1,279)



* Correct response is marked with an asterisk.

Figure 4. Which of the following populations are at an increased risk of experiencing serious side effect(s) associated with Xarelto? (N ranging from 1,284 to 1,286 across the 4 questions)

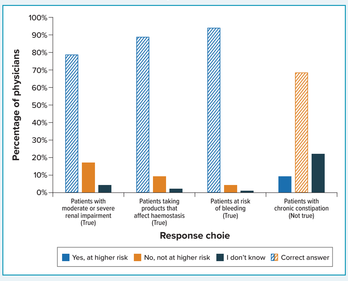
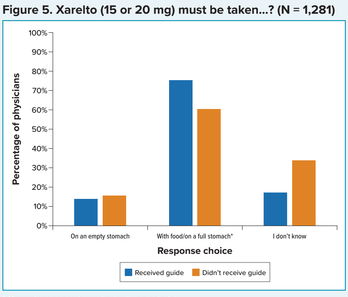
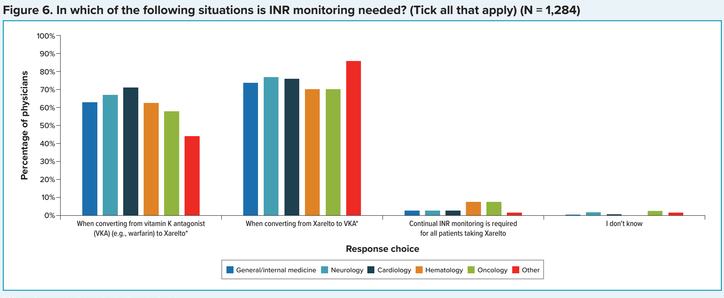


Figure 5. Xarelto (15 or 20 mg) must be taken...? (N = 1,281)



* Correct response is marked with an asterisk.

Figure 6. In which of the following situations is INR monitoring needed? (Tick all that apply) (N = 1,284)



* Correct response is marked with an asterisk.

DISCUSSION

- Physicians' knowledge was particularly high for questions related to the risks of side effects with rivaroxaban treatment and the use of rivaroxaban with special populations.
- Knowledge of more detailed aspects of administration (e.g., that rivaroxaban should be taken with food and dosing by indication) and monitoring (e.g., converting from VKA to rivaroxaban) was lower.
- There were no notable differences in correct response proportions between the physicians who participated in the previous waves (wave 1, wave 2, or both) and physicians who were new to the survey.

CONCLUSIONS

- Physician knowledge was highest on the most important risks and lower on more complex aspects of safe use that lend themselves to consultation of the PG and/or label rather than reliance on recall. Despite relatively low levels of reported receipt of the PG, the relatively high knowledge level and consistency over time suggest that the key safety information is available to treating physicians.

CONTACT INFORMATION

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