Non-Interventional Study (NIS) Primary Report Synopsis	
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Real world insights on the initiation and treatment duration of ticagrelor and other oral antiplatelets in patients with acute coronary syndrome in Belgium/Luxembourg (REWINDER)

NIS REPORT SYNOPSIS

Real world insights on the initiation and treatment duration of ticagrelor and other oral antiplatelets in patients with acute coronary syndrome in Belgium/Luxembourg (REWINDER)

Study Sites and Investigators

The study was conducted by 18 cardiologists from Percutaneous Coronary Intervention (PCI) and non-PCI hospitals in Belgium.

Total planned Study period	
Date of first patient in (first data entered in Case Report Form [CRF])	4 September 2014
Date of last patient last visit (last data entered in CRF)	30 January 2015
Date of data base lock	3 March 2015
Date of final study report	29 October 2015

Medicinal Products (type, dose, mode of administration) and concomitant medication

N/A

Publication:

None at the time of this report.

Objectives of this Non-Interventional Study

Primary objective:

- To evaluate the actual treatment persistence with oral antiplatelet (OAP) after an acute coronary syndrome (ACS) in the clinical practice in Belgium and Luxembourg.

Secondary objectives:

- To describe the most frequent reasons for OAP treatment switch, discontinuation or re-initiation.
- To identify who asked for the OAP treatment switch, discontinuation or re-initiation.
- To characterize the patient profile in terms of demographics, diagnosis, management strategies, comorbidities and concomitant medications to identify any association between patient profile and treatment duration.

Study design

REWINDER is a multicenter, non-interventional, retrospective study of patients treated with an OAP (ticagrelor, prasugrel or clopidogrel) while in hospital after an ACS event to collect real world insights on the initiation and treatment duration. All data were collected from patients' medical records. Cardiologists from 18 centers (PCI and non-PCI hospitals) in Belgium participated in data collection for this study. Once patients had been identified, they were informed of this study by means of a patient information letter before any data collection started. The cardiologists extracted the required data from their medical records and completed the CRF retrospectively. The target data coverage was 1 year after discharge. If the cardiologist's medical files covered a shorter period of follow-up data, the patient's general practitioner (GP) was contacted or the hospital medical records were consulted for completion of data.

Target patient population

Male and female patients from Belgium and Luxembourg, aged 18 years or more, discharged alive from hospital to home, following an ACS event (unstable angina [UA], ST-segment elevation myocardial infarction [STEMI] or non-ST-segment elevation myocardial infarction [NSTEMI]) and who were treated with an OAP (ticagrelor, prasugrel or clopidogrel) after the ACS event.

Study variable(s):

Primary variable:

- Actual treatment persistence with OAP after an ACS event in the clinical practice of Belgium and Luxembourg.

Other Variables:

- Person who asked for OAP treatment switch, discontinuation or re-initiation
- Reasons for OAP treatment switch, discontinuation or re-initiation
- Patient characteristics:
  - Demographics
  - Cardiovascular history and comorbidities
  - Concomitant medication
- Event (ACS) characteristics
- ACS treatment strategy

Statistical methods

All analysis were performed according to the Amended Statistical Analysis Plan (SAP) dated 18 March 2015.

Changes from protocol included identification of two analysis cohorts to ensure data integrity at the time of data cleaning.

All statistical analysis were essentially descriptive (no causal analysis) and consisted of descriptive statistics of variables and of cross-tabulations of multiple variables. No clinical interpretation can be taken from this study due to its descriptive nature.

Two population cohorts were identified for the purpose of analysis:

(i) Primary population included patients with OAP treatment status recorded with high certainty,

- Patients with a follow-up by cardiologist for at least 11 months
  and
- Patients with a follow-up less than 11 months or no follow-up but with an EXACT stop date (DD/MM/YY) either before or after last follow-up, regardless whether the information comes from medical records or GP.

(ii) Secondary population included patients with OAP treatment status recorded based on assumptions and uncertainty,

- Patients with a follow-up less than 11 months or no follow up but with an APPROXIMATE stop date (MM/YY)
  and
- Patients with a follow-up less than 11 months WITHOUT a recorded stop date (even if it is indicated that there is no change at 12 months).

The following variables were included in the statistical analysis:

- Patient (demographics, CV history and risk profile) and ACS characteristics (diagnosis categories, treatment strategies)
- Treatment persistence: number and proportion of patients who were still treated with OAP at a specific time point (3, 6, 9, 12 months)
- Reasons for change in the OAP treatment (stop, switch and/or re-initiation) and who prescribed the change.

Summary

Of 671 recorded CRFs, 560 were analyzed and 111 were excluded from analyses. The primary population included 314 patients, while the secondary population included 246 patients.

The actual treatment persistence with OAP after an ACS in the clinical practice of Belgium at 360 days from hospital discharge was 73% in the primary population and 87% in the secondary population, from a total number of 525 patients included in the analysis (Synopsis table 1).

Synopsis table 1. Treatment persistence at 90, 180, 270, and 360 days in the primary, secondary and overall populations

Timepoint	Primary population (%)		Secondary population (%)		Total (%)	
	Count	%	Count	%	Count	%
90 days	272	92	228	99	500	95
180 days	262	89	227	99	489	93
270 days	245	83	227	99	472	90
360 days	216	73	201	87	417	79

For the primary population, the most frequent reasons for stopping the treatment were physician's opinion/recommendation, followed by surgery and high bleeding risk. The most frequent reasons for switching OAP treatment before 11 months were side effects, while for re-initiation of the OAP treatment the most frequent reason was a new cardiovascular event.

For the primary population, the deciders for treatment stopping or switching to another OAP were in the majority of the cases interventional cardiologists followed by non-interventional cardiologists. The deciders for treatment re-initiation were in the majority of the cases surgeons. Treatment persistence was not found to be related to the final diagnosis.