Observational Study Protocol
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OBSERVATIONAL STUDY REPORT SYNOPSIS

Non-interventional study to obtain data on persistence and adherence to ticagrelor in patients with ACS in Serbia

Phase of development: Not Applicable – Observational study

Sponsor: AstraZeneca

Author:

[redacted]
Bulevar Vojvode Mišića 15
Belgarde, 11000
Serbia
[redacted]

[redacted]
Bulevar Vojvode Mišića 15
Belgrade, 11000
Serbia
[redacted]

Background/Rationale: Acute coronary syndrome (ACS) remains as a leading cause of mortality worldwide, despite improved cardiovascular disease management. [1,2]

Acute coronary syndromes (ACSs) represent a life-threatening range of clinical conditions that are almost always associated with the rupture of an atherosclerotic plaque and partial or complete thrombosis of the infarct-related artery. Platelet aggregation, induced by plaque rupture, is an important contributor to the generation of atherothrombotic events. (3)

Antiplatelet therapy is a key target in the treatment of ACS. [4–6] European Society of Cardiology (ESC) guidelines recommend dual antiplatelet therapy (DAPT) with low-dose acetylsalicylic acid (ASA) and a P2Y12 antagonist (ticagrelor, prasugrel or clopidogrel) to reduce the risk of acute ischaemic complications and recurrent atherothrombotic events in patients with ACS, regardless of revascularization with percutaneous coronary intervention (PCI) or not. Guidelines recommend DAPT inhibition to be maintained for at least 12 months unless contraindications are present, such

as a high risk of bleeding. [7,8] Ticagrelor was registered and introduced in Serbia in 2012. At that time clopidogrel was well established as OAP on the Serbian market, but prasugrel is still not registered. Up to date ticagrelor is not reimbursed by the National Health Insurance Fund (NHIF), clopidogrel (original and generics) is reimbursed.

As from July 2015 the AZ MC introduced patient support program with 50% price discount for patients, i.e. 50% of price is covered by AstraZeneca. This patient support program is planned to last until Brilique® (ticagrelor) reimbursement, which is expected to happen by the end of 2018. Foreseeing future reimbursement status of ticagrelor will be similar, with 50% patient co-pay.

In Serbia, there is no source of possible retrospective data collection for ACS patients, i.e. so far no active ACS patient registry available. National registry with planned follow up has been recently established, but without sufficient follow up data. Medical records are not standardised at national level, they are institution-specific). Thus there is no source to obtain clear data on adherence and persistence to OAP in real life setting. To date, there is no local data on adherence and persistence to ticagrelor after an ACS among Serbian patients.

Therefore, getting local data on persistence and adherence to ticagrelor and better local understanding of factors contributing to nonadherence of ticagrelor may help inform actionable opportunities to optimize longitudinal ACS patient outcomes.

This non-interventional study is aimed to collect in prospective manner the primary patient data related to persistence and adherence to ticagrelor treatment in ACS patients in Serbia and the reasons of OAP treatment switch, discontinuation, or re-initiation.

Objectives: The aim of the study is to describe actual persistence-duration of ticagrelor therapy and adherence to ticagrelor in ACS patients, counting from the ACS-hospital discharge (index) date, in everyday clinical practice in Serbia.

Study design: Open label, multicentre, single country, non-interventional, observational study with prospective data collection

Data source: Source of documentation: medical records, 3 patients' questionnaires (one related to persistence, one related to adherence and one related to lifestyle measures)

Study population: 269/9

Inclusion Criteria: • ≥ 18 years of age

• diagnosed with ACS - STEMI or NSTEMI or unstable angina, invasively or non-invasively treated

• Patients already on treatment with ticagrelor at least for 1 month and no longer than 3 months prior to study initiation. Enrolment in this study must not be trigger for ticagrelor initiation.

• read and signed the Informed Consent Form

Exclusion criteria:

- Any contraindications as per approved SmPC of Brilique
- Patients with life-threatening conditions which could disable patients to comply with scheduled visits and/or not able to fill in the patient questionnaires.

Statistical methods: Since the study is a non-interventional, it represents the everyday practice. Ticagrelor usage is in line with drug's Summary of Product Characteristic

Results: Out of 269 patients in total who were included into 12 follow-up months, 50 patients (18,6%) terminated the treatment with Brilique 90mg. Within 20 patients at visit after 6 months , it was stated that the reason for termination (or changing the therapy) was: HCP's advice (9), personal decision (4) bleeding (4) bruising (1), CABIG (1), surgical intervention (1).At the visit after 12 months the reason for termination of Brilique therapy were as follows: bleedings(2), price of Brilique (8), personal decision (5), more than 12 months since MI (10). Nine patients switched to another OAT

Conclusion: N/A

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