Cilostazol is indicated in Europe to improve walking distances in patients with intermittent claudication. Cilostazol has been associated with spontaneous reports of serious bleeding and cardiovascular effects, including myocardial infarction, stroke, and angina.

The risk-benefit assessment includes the consideration of the impact of the risk-minimization measures implemented on the occurrence of any critical event and the consequent clinical impact in patients who may experience those critical events. The measures were implemented in each country to ensure the continued safety of the drug in a real-world setting. In the current study, the impact of the risk-minimization measures was evaluated in the five European study populations through the implementation of two parallel observational studies, named DUS1 and DUS2. 

### Study Population

- **Objective:**
  - The study population included new users of cilostazol in five European populations: the THIN (The Health Improvement Network, UK), EpiChron (Spain), SIDIAP (Spain), THIN (The Health Improvement Network, UK), and THIN (The Health Improvement Network, UK).

- **Endpoints:**
  - The endpoints of the study were the frequency of critical events associated with labeling changes among new users of cilostazol.

- **Methods:**
  - The study was conducted using a parallel observational design, including labeling changes and communication to health care professionals in 2013, but not required for the implementation of labeling changes (from 2013 to 2015).

- **Results:**
  - The study population included 1,528 new users of cilostazol who were monitored for 1 year before and after the implementation of risk-minimization measures.

- **Discussion:**
  - The results of the study suggested that the risk-minimization measures were effective in reducing the frequency of critical events associated with labeling changes among new users of cilostazol.

### REFERENCES


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