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Original article

Cost analysis of bivalirudin versus reference anticoagulants without GP IIb/IIIa inhibitors in patients undergoing percutaneous coronary intervention for acute coronary syndrome in routine clinical practice. Pompidou registry

Analyse des coûts de la bivalirudine versus les anticoagulants de référence sans anti-GPIIb/IIIa associés chez les patients ayant une angioplastie coronaire pour un syndrome coronarien aigu dans la pratique clinique courante. Registre Pompidou

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Abstract

Randomized controlled trials have shown improved short-term bleeding outcomes for bivalirudin compared to other anticoagulant in patients undergoing percutaneous coronary intervention (PCI) for acute coronary syndrome (ACS). This study analyzed the cost/efficacy profile of bivalirudin-based anticoagulation strategy versus non bivalirudin-based anticoagulant strategy without use of GP IIb/IIIa inhibitors in routine clinical practice. From January 2009 to December 2010, 216 patients who underwent PCI for ACS at hospital Georges-Pompidou without GP IIb/IIIa inhibitors were studied. Of these patients, 24 (11%) received bivalirudin and 192 (88%) received others anticoagulants (mainly unfractionated heparin or low molecular weight heparin). Ischemic events and bleeding or transfusion were slightly lower in bivalirudin group (0 vs. 4.2%, $P = 0.60$ and 4.2 vs. 8.9%, $P = 0.70$, respectively). In spite of a higher cost of the medication, the overall cost of the bivalirudin strategy was slightly lower (9167 ± 3688 € vs. $14{,}016 \pm 14{,}749$ €, $P = 0.23$), in relation with a shorter average duration of the hospital stay. In conclusion, in this limited, single-center, population of patients with ACS, the clinical efficacy and safety of bivalirudin appeared at least as good as that of reference anticoagulants in real world clinical practice, with no increase in overall costs.

Keywords: Bivalirudin; Acute coronary syndrome; Percutaneous coronary intervention; Economic analysis

Résumé

Plusieurs essais randomisés ont démontré les bénéfices à court terme de la bivalirudine par rapport aux autres anticoagulants sur les saignements chez les patients ayant une angioplastie coronaire dans le cadre d'un syndrome coronarien aigu (SCA). Cette étude analyse l'impact économique d'une stratégie reposant sur l'utilisation de la bivalirudine par rapport aux autres traitements anticoagulants utilisés sans anti-GPIIb/IIIa. Entre janvier 2009 et décembre 2010, 216 patients ayant eu une angioplastie coronaire pour un SCA à l'hôpital européen Georges-Pompidou, non traités par anti-GPIIb/IIIa, ont été étudiés. Chez ces patients, 24 (11 %) ont reçu de la bivalirudine et 192 (88 %) ont reçu un autre traitement anticoagulant (principalement de l'héparine non fractionnée ou une héparine de bas poids moléculaire). La survenue d'événements ischémiques et des saignements ou transfusions était légèrement moins fréquente chez les patients traités avec la bivalirudine (0 vs. 4.2 %, $p = 0.60$ et 4.2 vs. 8.9 %, $p = 0.70$, respectivement). Malgré un coût du médicament plus élevé, les coûts globaux étaient légèrement inférieurs chez les patients traités avec la bivalirudine (9167 ± 3688 € vs. $14\,016 \pm 14\,749$ €, $p = 0.23$), en raison d'une durée d'hospitalisation plus réduite. En conclusion, dans cette

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étude monocentrique, l'efficacité clinique et la tolérance de la bivalirudine sont comparables aux autres traitements anticoagulants de référence dans la pratique courante, sans augmentation significative des coûts.

Mots clés : Bivalirudine ; Syndrome coronarien aigu ; Angioplastie coronaire ; Analyse économique

1. Introduction

Optimal antithrombotic treatment in patients undergoing percutaneous coronary intervention (PCI) is crucial to balance risk of bleeding after PCI versus ischemic complications. Bivalirudin, a direct thrombin inhibitor, has been investigated especially in patients with acute coronary syndrome (ACS) with or without ST-segment elevation [1–4]. Recently, the Harmonising Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial has assessed the impact of bivalirudin, compared with a combination of unfractionated heparin (UFH) and glycoprotein IIb-IIIa inhibitors (GPI) in patients with PCI for ST-elevation myocardial infarction (STEMI), and has shown a reduced bleeding risk and improved survival up to 3 years after the acute event [4]. This has led to a grade I recommendation in the most recent STEMI guidelines of the European Society of Cardiology [5]. In spite of these favourable clinical results, the use of bivalirudin has remained marginal in France [6–8], possibly because of the cost of the medication, even if the use of bivalirudin is cost-effective [9–13]. In this context, the aim of this study was to analyze cost issues in patients without GPI, according to the use of bivalirudin, in a single-center ACS registry (Pompidou registry).

2. Materials and methods

2.1. Population and methods

The Pompidou registry is an observational registry of patients admitted to the intensive cardiac care unit (ICCU) of hôpital européen Georges-Pompidou (HEGP, Paris, France) for an ACS in 2009–2010. The aims of the study were to:

- characterize clinical management patterns associated with treating a broad spectrum of high-risk PCI patients observed in typical French hospital practice. A particular focus of this study will be to characterize post-procedural bleeding events typically experienced by high-risk PCI patients;
- identify the key components of resource utilization associated with the management of high-risk PCI patients and their post-procedural events;
- determine and apply direct French unit-cost data to the key components of resource utilization, with a view to building aggregate costs of treatment and post-procedural events, such as bleeding;
- enable estimates of parameters and data inputs to populate health economic model(s) designed to evaluate treatment strategies for similar patient populations in France (e.g. a bivalirudin-based strategy versus a heparin-based strategy).

Inclusion criteria were: high-risk population admitted to the ICCU, and defined as: unstable angina (UA), non ST-segment elevation myocardial infarction (NSTEMI) or STEMI patient presenting to the ICCU at the HEGP, requiring rapid coronary angiogram and PCI if necessary (≤ 48 hours). Non-adult patients were excluded and, for the present analysis, patients who received GPI either pre-hospital or in hospital were excluded.

Participating in the registry did not change the therapeutic approach of the cardiologist in any way. The registry was conducted in compliance with Good Clinical Practice (GCPs), French Law and the French data protection law. The protocol was reviewed by the Committee for the Protection of Human Subjects in Biomedical Research (CCPPRB) of HEGP and the data file of the Pompidou registry was declared to the Commission Nationale Informatique et Liberté (CNIL).

2.2. Data collection

Data of consecutive patients admitted in 2009 and 2010 were prospectively collected and recorded in a specific electronic Case Record Form. Special attention was given to bleeding events and costs. The duration of hospitalization in ICCU and in the general cardiology ward were recorded for each patient.

2.3. Cost analyses

Costs were calculated by comparing the cost of the hospital stay (cost per day in ICCU: 2553 €; cost per day in general ward: 1146 €). We considered only the events and costs related to the stay at HEGP (i.e. we did not analyze the costs associated with hospitalization in a rehabilitation unit). Also, the cost of antithrombotic medications was calculated individually for each patient, taking into account the costs of bivalirudin, GPI, transfusions, and closure devices. When the total dose of the medication was missing, a theoretical cost was used (e.g. 600 € for abciximab). The costs of UFH, and low molecular weight heparin (LMWH) was considered to be negligible, and prescription rates were little different in the patients receiving or not bivalirudin, so that they were not taken into account in the cost-evaluation models.

2.4. Statistical analyses

Comparisons were made between the patients treated with bivalirudin initially, and those receiving other antithrombotic medications. Data are presented as numbers and percentages for discrete variables and as mean ± standard deviation (and/or median and interquartile range) for continuous variables. Between group comparisons use the chi^2 test or Fisher exact test when appropriate for discrete variables, and Student's *t* test or