Economic performance of dabigatran etexilate for primary VTE prevention following total hip and knee replacement surgery in Italy

Introduction

Thromboembolic events (VTE) represent a quite common and dangerous complication of major orthopedic surgery, especially in total hip replacement (THR) and total knee replacement (TKR) procedures. In the last years, thromboprophylaxis with low molecular weight heparins (LMWHs) has become the standard approach for the prevention of these events, although the optimal duration of the prophylaxis is still under debate.

Dabigatran etexilate (DBG), a direct and reversible thrombin inhibitor, has proven its non-inferiority with respect to enoxaparin, a LMWH, in the prevention of VTE in patients undergoing THR and TKR, in the RE-NOVATE [1] and RE- MODEL trials [2], respectively.

Objective

The objective of the present study is to estimate cost-effectiveness and cost-utility of DBG compared to standard care for the prevention of VTE in THR and TKR patients in Italy, in order to contribute a rational base to the decisions making process in this field.

Methods

The evaluation has been performed by adapting a pharmacoeconomic simulation model originally developed for the UK by Wolowacz et al. [3] to the Italian health care setting.

Clinical outcomes, including incidences of VTE and treatment-related adverse events, were extrapolated from head-to-head, phase III trials of DBG vs enoxaparin. For the other LMWHs, indirect comparisons were performed on the basis of equal effectiveness assumptions.

The adaptation involves cost and demographic characteristics, leaving clinical and utility data unvaried. Costs are taken from national observational studies, where available. Otherwise, current prices and tariffs are applied. Resources consumption is derived from practice guidelines or taken from those estimated for the UK model.

According to the prevalent national practice extended prophylaxis has been considered for both surgical procedures, in order to reflect national prevalent praxis. DBG in the post-discharge period is dispensed directly by the hospital pharmacy. LMWHs may be dispensed in several ways: directly by the hospital, by territorial dispensing centers or taken from those estimated for the UK model.

Time horizon of the analysis is patients’ lifetime.

Results

Compared to LMWHs, DBG is associated to an expected increase of 0.019 LYs and 0.014 QALYs per THR patient and of 0.024 LYs and 0.019 QALYs per TKR patient. DBG-related cost is lower than competitors in both procedures, with a mean difference ranging between € 82 and €109 for THR, and €100 and €135 for TKR, depending on the considered comparator. Higher acquisition costs for DBG are completely offset and inverted by avoided administration expenses and, less importantly, by savings on VTE management (Table II).

Probabilistic sensitivity analysis (PSA) estimates that, for a willingness to pay threshold of €30,000 (~33,500/QALY), DBG is associated to a probability of being cost-effective of about 98% for THR and of 90% for TKR (Figure 1).

Conclusions

On average, basing on an adaptation to the Italian demographics, costs, and clinical practice of a simulation model originally developed for the UK, DBG dominates the LMWHs in the prevention of VTE after THR and TKR procedures, as it’s expected to be cost-saving and non-inferior in terms of efficacy and safety.

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References

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