PHARMACOECONOMIC ASSESSMENT OF APIXBAN VERSUS STANDARD OF CARE FOR THE PREVENTION OF STROKE IN ITALIAN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS

Background

- Ischemic and hemorrhagic strokes are the main complication of non-valvular atrial fibrillation (NVAF) [1].
- Until recently, warfarin (vitamin K antagonist [VKA]) was the standard of care for stroke prevention in NVAF patients, with aspirin recommended for low-risk and VKA-unsuitable patients [2].
- Apixaban, a novel oral anticoagulant agent (NOAC), has proven clinically superior in stroke and systemic embolism prevention in adult NVAF patients with one or more risk factors [3,4], and guideline recommendations changed accordingly [5].

Objective

- The objective of this study was to evaluate the cost-effectiveness of apixaban in the prevention of thromboembolic events in NVAF patients relative to standard of care (warfarin or aspirin) from the Italian National Health System (SSN) perspective.

Methods

- A previously published Markov model with cycles of 6 weeks was adopted for Italian NVAF patients [6]. The analysis was modeled for a lifetime horizon (Figure 1).
- Clinical effectiveness and safety data of apixaban versus warfarin, in NVAF patients suitable for VKA, and apixaban versus aspirin, in patients unsuitable for VKA, derived from head-to-head randomized trials [3,4].
- Main clinical events considered in the model were ischemic and hemorrhagic stroke, systemic thromboembolism, myocardial infarction, bleeds (both major and clinically relevant minor), cardiovascular hospitalizations, and death. Expected survival was projected beyond trial duration using national mortality data [7] adjusted for individual clinical risks [6] and weighted by utility weights for health states derived from literature [8].
- Direct health care unit costs (€), updated at 2013 [7], included drug acquisition [8], routine visits [9], ischemic and hemorrhagic strokes [10], myocardial infarctions [11], bleeds management and cardiovascular hospitalizations [12], and other health care costs associated with AC management [12].
- Costs and health gains accruing after the first year were discounted at an annual 3.5% rate.
- Deterministic and probabilistic sensitivity analyses (DSA & PSA) were carried out to evaluate the effect of inputs uncertainty.

Results

- Incremental LYS (0.19/0.31), QALYs (0.20/0.28), and costs (€1,104/€1,932) were predicted with the use of apixaban relative to warfarin and aspirin, respectively [Tables I and II].
- The incremental cost effectiveness ratios (ICERs) of apixaban compared to warfarin and aspirin were €5,607 and €6,794 per QALY gained, respectively [Tables I and II].
- DSAs indicated that results were most sensitive to variations of the absolute risk reduction for cardiovascular events with apixaban (Figures 3).
- The PSA substantially confirms the findings of the main analysis (Figure 4). The probability of apixaban being cost-effective relative to warfarin and aspirin is 93% and 95%, respectively, for a WTP threshold of €20,000 per QALY gained.

Conclusions

- Apixaban is expected to increase life expectancy and quality-adjusted life expectancy, but also costs dedicated to Italian NVAF patients, as compared to standard of care.
- The resulting ICERs have 93-95% probabilities of being below the conventional 20k/QALY threshold of the SSN, indicating efficient allocation of health care resources.

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References

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