Prevention with picotamide and aspirin in patients with type 2 diabetes mellitus and peripheral arterial disease: a pharmacoeconomic evaluation

Background

- Type 2 diabetes mellitus (DM) and peripheral arterial disease (PAD) are two very relevant cardiovascular (CV) risk factors, which can often be found concurrently in the same patient.
- The DAVID trial [1], a double-blind, randomized, aspirin (ASA)-controlled study, demonstrated that the use of picotamide, a thromboxane A2 synthase and receptor dual inhibitor, is associated with lesser CV mortality and mortality in this type of patients in comparison to ASA, considered the standard antiplatelet agent.

Objective

- To estimate clinical and economic impacts of the use of picotamide versus ASA for the treatment of type 2 diabetes mellitus and peripheral arterial disease in the Italian health care setting.

Methods

Model description

- We developed a simple Markov model to describe the dynamics between the two states: patient with DM and PAD and death. Time horizon extends over patients lifetime and cycle duration is 1 month.
- Overall mortality rates of the picotamide and ASA group are obtained extrapolating survival data from the DAVID trial on mortality tables of the general Italian population [2].
- Efficacy of the treatment is measured in terms of average life years gained (LYs). Pharmacoeconomic evaluation is conducted in terms of Cost Efficacy Analysis: incremental cost efficacy ratio (ICER) of picotamide vs. ASA is calculated.

Costs

- Costs are evaluated taking into account pharmaceutical costs for the treatment and direct medical costs due to relevant CV events (myocardial infarction, stroke) and adverse events (gastrointestinal haemorrhage).
- In current Italian prices and reimbursement policy, the cost for ASA therapy in type 2 DM and PAD patients is totally born by NHS, while that for picotamide is not. This means that in the current scenario the cost of picotamide is out-of-pocket for patients.
- We developed an alternative hypothetical scenario in which picotamide is directly distributed by hospital pharmacies of-pocket for patients.
- CV and adverse event costs are obtained from an Italian study [3]. Cost and adverse event treatment are evaluated based on current prices and tariffs [3, 4].
- Cost related to CV events and consequent monthly follow-up are derived from an Italian study [5].
- Cost of PAD and stroke are based on hospitalization cost for the Italian INAIL database [6]. Costs are evaluated taking into account pharmaceutical costs for the treatment and direct medical costs due to relevant CV events (myocardial infarction, stroke) and adverse events (gastrointestinal haemorrhage).

Sensitivity analysis

- A one-way deterministic sensitivity analysis has been performed applying ± 5% range on mortality, CV events and adverse event rates, and ± 10% range on all costs.

RESULTS

Sensitivity Analysis

- Our model shows that life-long treatment with picotamide could improve life expectancy of about 22 years per patient. This is obtained at an increased cost of about € 18,600 and € 9,200 per patient in the current scenario and the direct distribution scenario, respectively. Resulting ICERs are 8,502 and 4,207 €/LY.
- One-way sensitivity analysis, conducted for the direct distribution scenario, showed a good stability of the model. Main parameters that can influence the final result are overall mortality rate and picotamide cost. In worst case a 5% variation in overall mortality rate can lead to a 14.5% variation in ICER.

Conclusions

- The current scenario, which reflects current prices and reimbursement policy, yielded an ICER of about 8,500 euro/LY saved, which falls below conventionally adopted willingness to pay thresholds. This cost, however, is totally born by the patient, while the savings on health care expenditures for avoided events (and less ASA) benefit the national health service (NHS). These results may help the physician in explaining the consequences of this choice to his/her patients, facilitating a fully-informed choice. The availability of a theoretical model allowed to explore some alternative scenarios (direct distribution), that indicate that the ICER can be further lowered and the economical burden better distributed through policy changes.
- In conclusion, the pharmacoeconomic model indicated that picotamide is likely to be a cost-effective option for CV mortality and morbidity prevention in patients with concurrent type 2 DM and PAD and that the level of adoption of this strategy will depend on willingness to pay and policy priorities of the NHS and patients themselves.

References

5. Capri S, Perlini S, Cost-effectiveness in Italy of preventive treatment with ramipril in patients at high risk of cardiovascular events. Efficacy of the treatment is measured in terms of average life years gained (LYs). Pharmacoeconomic evaluation is conducted in terms of Cost Efficacy Analysis: incremental cost efficacy ratio (ICER) of picotamide vs. ASA is calculated.