ECONOMIC ANALYSIS OF VEDOLIZUMAB VERSUS USTEKINUMAB IN THE TREATMENT OF CROHN'S DISEASE IN ITALY.

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Abstract

Background

Patients suffering from Crohn's Disease (CD) experience an alternation of remission phases and periods of disease exacerbation. The main symptoms are diarrhea, with or without blood loss, abdominal pain, fatigue, dehydration and weight loss. Corticosteroids and immunosuppressants allow to treat symptoms and are associated with side effects that heavily compromise the quality of life of patients. On the other hand, biologic drugs can modify the natural history of the disease and present a favorable safety profile. Among biologics, vedolizumab (VDZ) is the first humanized antibody which selectively inhibits leukocyte migration into the intestinal mucosa without interfering with other organs; ustekinumab (UST) is a fully human antibody which inhibits the bioactivity of human cytokines interleukin.

Aim

The aim of the present analysis is to assess the cost-utility of VDZ compared to UST, in the treatment of patients with moderately-severely active CD.

Methods

For the analysis a Markov model with a lifetime-horizon was used, with cycles of 8 weeks. Health conditions are defined according to the CDAI scores: "remission"; "response" ; "moderate-to-severe disease"; "severe" . Transition probabilities, adverse events probabilities and discontinuations due to adverse events were derived from the available literature both for vedolizumab and ustekinumab arms. Following the Italian NHS perspective, only direct healthcare costs were considered in the analysis: (1) drug acquisition price, (2) drug administration (2), adverse event management, (3) hospital costs for surgery and post-operative course and (4) management of different health states (i.e. follow up visits). In order to test the robustness of the results, both deterministic (DSA) and probabilistic (PSA) sensitivity analyses were performed.

Results

VDZ showed greater efficacy than UST, in terms of QALYs. Over a life-time horizon, VDZ was associated a gain of 11.22 QALYs per patient, whilst with UST the gain was 11.13 (with a gain of 0.09 QALYs per patient). Concerning costs, VDZ was associated a saving of € 39,882 compared to UST. In the sensitivity analysis, no simulations reported a positive incremental cost for VDZ: less than 4% associated negative incremental costs with negative incremental QALYs.

Conclusion

VDZ is to be recommended for the treatment of CD patients