1 INTRODUCTION

Ulcerative colitis (UC) is a chronic inflammatory disease which main symptoms are abdominal pain, bloody diarrhoea and alternated periods of remission and relapses. UC is known to be a costly disease with great impact on patient’s quality of life and productivity. Current treatments for moderately-to-severely UC include conventional therapy (such as steroids or thiopurines), immunosuppressant, biological drugs and the more recent oral small molecules such as tofacitinib, a Janus Kinase inhibitor. Surgery is considered the last option. According to the American College of Gastroenterology clinical guidelines, patients who are primary nonresponders to an anti-TNF should be evaluated and considered for alternative mechanisms of disease control (e.g., in a different class of therapy) rather than cycling to another drug within the anti-TNF class. Thus, given the promising spectrum of new emerging therapeutic options, economic evaluations are needed in order to help healthcare systems making informed decisions.

2 OBJECTIVE

To evaluate the cost-effectiveness of using tofacitinib for the treatment of moderate-to-severe active ulcerative colitis after failure/intolerance to a first line of biologic treatment, from the Spanish National Health System (HNSI) perspective.

3 METHODS

A panel of experts defined three different scenarios to compare tofacitinib vs adalimumab, infliximab and vedolizumab treatments after failure/intolerance to a biologic drug (Fig. 1). A markov model was developed with cycles of 8 weeks and a lifetime horizon (Fig. 2). Two different treatment periods were considered: induction and maintenance.

3.1 Induction

A hypothetical cohort of 1,000 patients can switch from 5 different health states, defined according to the Mayo’s scale score as follows (Fig. 2):
- Remission (Mayo score = 0–2; and all subscores = 0)
- Response (decrease in baseline Mayo score of ≥3 and at least a 30%; with a decrease in rectal bleeding subscore of ≥2 point or a value of 0–1)
- Moderate-to-severe active UC
- Remission after surgery
- Death

Patients can change to second line treatment: 1) if they remain with active UC after induction; or 2) if there is a loss of response under maintenance treatment (patients shift to active UC state again).

The model considered an annual rate for surgery of 1.44%, with the possibility of post-surgery complications.

Patient profile was defined based on characteristics of patients included in tofacitinib’s OCTAVE induction 1 & 2 clinical trials (Table 1).

Comparative efficacy data were inferred from a network meta-analysis, where specific analyses for induction and maintenance periods were considered.

Utilities were obtained from literature.

Serious adverse events were included: serious infections – upper respiratory tract infections – tuberculosis – malignancies – herpes zoster – acute reaction after infusion – infusion site reactions.

3.2 Maintenance

Figure 2: Structure of the model

3.3 Cost

Costs associated with tofacitinib are listed in Table 1. The drug was considered to be effective if the remission or response was maintained for at least 2 cycles.

4 RESULTS

Comparison of costs and QALYs between the treatment with tofacitinib, adalimumab, infliximab and vedolizumab is presented in Table 2. When compared to adalimumab, tofacitinib had a lower efficacy thus increasing treatment discontinuation and thereby reducing acquisition costs.

The probability of tofacitinib being the cost effective was above 70% in comparison to infliximab and vedolizumab (Table 3).

5 DISCUSSION

According to our results, after failure or intolerance to biologic therapy, tofacitinib is a cost-saving therapy for the treatment of moderate-to-severe UC patients with similar QALY gains vs infliximab and vedolizumab; besides being a cost-effective alternative when compared to adalimumab.

REFERENCES

22 Rubín DT et al. UEGW 2018.

DISCLOSURE

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