A comprehensive database on drug assessments and HTAs in Spanish. An exploration in psoriatic disease.

Introduction

- In Spain, drug assessments are performed by different entities at the regional and hospital level. At the national level, the Spanish Agency for Medicines and Health Products (AEMPS) performs the therapeutic positioning reports for new drugs.
- These evaluations include parameters such as efficacy, safety, and cost, and they are based on pharmacological evidence and professional recommendations for the respective use of new drugs.
- In this article, a drug review was conducted to identify the added therapeutic value of different drugs prescribed in psoriasis.

Materials and Methods

- A database has provided an overview of the evaluation of new medicines in Spain. This database summarizes the outcome measures in terms of efficacy, adverse events, and economic parameters of these drugs in order to determine their therapeutic positioning given a clinical indication.
- This database also includes recommendations on the use of these drugs and evaluates the current treatment algorithms according to clinical guidelines and protocols.
- In the example of drug review performed for psoriatic disease, four clinical guidelines were reviewed in order to determine the pharmacological treatments available and the current treatment algorithms of disease.
- To draw conclusions on the use of drugs for psoriatic disease, all drug assessments and therapeutic positioning reports published in Spain were identified. This corresponds to four therapeutic positioning reports from the AEMPS and 33 reviews at the regional and hospital levels (Table 1).

Table 1. List of drug assessment reports on psoriatic disease

<table>
<thead>
<tr>
<th>Name of the drug</th>
<th>Active substance</th>
<th>Pharmacological classification</th>
<th>Approval date</th>
<th>Drug assessment reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAZILO 2% mousse for injection in pre-filled auto-injector pumps</td>
<td>Infliximab</td>
<td>Anti-TNF-alpha monoclonal antibody</td>
<td>2005</td>
<td>AEMPS</td>
</tr>
<tr>
<td>GOUSCHY 150 mg/ml mousse for injection in pre-filled auto-injector pumps</td>
<td>Adalimumab</td>
<td>Anti-TNF-alpha monoclonal antibody</td>
<td>2005</td>
<td>AEMPS</td>
</tr>
<tr>
<td>BERTIN 250 mg/ml intraarticular injection</td>
<td>Vincristine</td>
<td>Antineoplastic</td>
<td>2005</td>
<td>AEMPS</td>
</tr>
<tr>
<td>OTEZLA 20 mg filmtabl.</td>
<td>Otezolizumab</td>
<td>Anti-PD-L1 monoclonal antibody</td>
<td>2016</td>
<td>AEMPS</td>
</tr>
<tr>
<td>REMUIA 100 mg powder for reconstitution for injection</td>
<td>Eculizumab</td>
<td>Anti-C5 monoclonal antibody</td>
<td>2016</td>
<td>AEMPS</td>
</tr>
<tr>
<td>ENPILIN 10 mg powder and solution for injection</td>
<td>Abiciximab</td>
<td>Anti-IgG monoclonal antibody</td>
<td>2016</td>
<td>AEMPS</td>
</tr>
<tr>
<td>EULTRA-65 mg powder for solution for injection</td>
<td>Ustekinumab</td>
<td>Anti-IL12 and IL23 monoclonal antibody</td>
<td>2016</td>
<td>AEMPS</td>
</tr>
<tr>
<td>EULOIN PLUS 15 mg + 3 mg/ml filmtabletta / 1 box of 48 tablets</td>
<td>Secukinumab</td>
<td>Anti-IL17 monoclonal antibody</td>
<td>2017</td>
<td>AEMPS</td>
</tr>
</tbody>
</table>

Results

- The current therapies included in clinical guidelines are focused on symptom control of the psoriatic disease. The selection of a treatment will be individualized for each patient, considering their characteristics, extension and location of lesions, the course and disease evolving status, response to previous treatments and the level of scientific evidence of the available therapies (Figure 1).

Figure 1. Pharmacological treatments for psoriasis according to clinical guidelines

Table 2. Review of drugs evaluated in psoriasis

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic positioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td></td>
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</tbody>
</table>
- Infliximab has demonstrated superiority in terms of efficacy versus placebo and appears to be sustained in the long term. The most effective BT for moderate to severe psoriasis is Infliximab, followed by ustekinumab and secukinumab, adalimumab, etanercept and apremilast.
- In the long term, infliximab, adalimumab, ustekinumab and etanercept can be considered equivalent therapeutic alternatives and the selection of treatment will be based on efficacy criteria.
- Secukinumab and ustekinumab are considered equivalent treatments, adalimumab and etanercept in moderate to severe psoriasis, while biologic treatment with apremilast is being considered the last therapeutic option when the other available therapies cannot be used.
- The two BT agents assessed perform two therapeutic alternatives more in TN.
- Regarding the safety profile of previous drugs, the two BT agents are much more resistant to the administration and injection compared to the other therapeutic alternatives.
- Regressing on economic impact, the positioning anti-TNF agents in terms of cost-effectiveness results would be ordered as follows: etanercept > adalimumab > infliximab > ustekinumab.

Conclusions

- The database on drug assessments has shown to be an effective tool to evaluate the outcome measures of new drugs, providing key criteria for future drug assessments that will enhance the successful market access of a new drug.

Recommendations for future drug assessments

- The therapeutic positioning of biologic drugs should be re-evaluated in future drug assessments based on the development of new therapeutic alternatives for systemic treatment, in order to obtain more conclusive efficacy outcomes.
- Most of the drug assessments included in this study are aimed to analyze efficacy outcomes in the short term and it would be recommended to develop more studies that evaluate efficacy and safety in the long term.
- Taking into consideration the chronic condition of psoriasis and the high impact in quality of life of these patients, it would be recommended to include the variable QoL in new drug evaluations in order to assess the effect of biologic drugs at different levels (physical, emotional, sexual...).
- Given the lack of drug evaluations in pediatric and young population, it is necessary to conduct clinical trials that would provide direct evidence in terms of efficacy of the available drugs, focusing on pharmacologic drugs. This pharmacological evidence would be very helpful to define specific guidelines for the management of this group of patients.

References