

Aim and objectives The objective of this study was to describe the current status of clinical trials (CT) for AD in our hospital pharmacy service and to analyse the investigational drugs.

Material and methods An observational descriptive retrospective study was carried out in a tertiary academic hospital. All active CT in the neuropsychology service from 1 January 2014 to 31 March 2019 were reviewed. Collected data were total number of CT; total number of included patients; demographic data; total number of CT classified by CT status (active/closed); clinical trial phase; therapeutic targets (reduction of amyloid plaques (AP)/precursor amyloid peptide (PAP) attack/inhibition of GLYT1 transporter/selective antagonism of 5-HT6 receptor/partial selective agonism of α_7 nicotinic receptor); administration route (oral/intravenous/subcutaneous); clinical trials with results; and type of result (positive/negative).

Results Twelve CT were analysed involving a total of 59 patients (mean 5 patients per clinical trial (rank 0–8)), 34 (57.6%) women with a mean age of 77.4 years (95% CI 71.5–84.7). Six (50.0%) CT were active; 3 (25.0%) CT were phase II trials and 9 (75.0%) were phase III trials. Therapeutic targets were reduction in AP 5 (41.7%), attack of PAP 3 (25.0%), inhibition of GLYT1 transporter 1 (8.3%), selective antagonism of 5-HT6 receptor 2 (16.7%), partial selective agonism of α_7 nicotinic receptor 1 (8.3%); route of administration oral 7 (58.3%), intravenous 1 (8.3%) or subcutaneous 4 (33.3%); and 3 (25.0%) CT had results, all of which were negative (3 (100%)).

Conclusion and relevance

- The highest number of active CT were phase III trials.
- Only 25% of CT had results and all were negative.
- Almost 60% of CT studied oral administration, which was patients' preference.
- There were a total of five therapeutic targets but more than 40% of the CT evaluated the reduction in APs.
- Based on these results, we should rethink the research on Alzheimer's disease before continuing to develop clinical trials with the same therapeutic target.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-141 EFFECTIVENESS OF IMMUNOTHERAPY IN SEVERE UNCONTROLLED ASTHMA

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Background and importance It is estimated that asthma affects 4.9% of adults in Spain and 3.9% are classified as severe uncontrolled asthma (SUA). Omalizumab, mepolizumab, reslizumab and benralizumab are monoclonal antibodies indicated in the treatment of SUA in adults.

Aim and objectives To analyse the effectiveness and improvement in quality of life in patients with SUA treated with monoclonal antibodies in a second level hospital.

Material and methods A retrospective observational study was conducted of all patients with SUA who received monoclonal antibody therapy from August 2011 to September 2019. Age, gender and clinical data (treatment duration, ingestion of oral corticosteroids (OCS), asthma control test (ACT), presence of

exacerbations requiring OCS and hospitalisations related to asthma) were recorded before starting immunotherapy and at the last follow-up visit. Effectiveness was evaluated as a reduction in OCS, exacerbations and/or hospitalisations. ACT was used to evaluate improvement in quality of life, with a score of at least 20 considered good control of asthma.

Results Forty-eight patients were included, 70.8% (n=34) were women, mean age was 56 years (23–79), and 75% (n=36) were treated with omalizumab, 18.7% (n=9) with mepolizumab, 4.2% (n=2) with reslizumab and 2.1% (n=1) with benralizumab. Mean duration of treatment was 31, 9, 8 and 1 month, respectively. Effectiveness was not evaluated in three patients due to lack of information. Treatment was discontinued in 7 patients for inefficacy, 3 for tolerance, 1 for adherence and 1 for hospital referral. Three patients were switched from omalizumab to mepolizumab during the study. Before starting immunotherapy, 24.3% (n=10) of patients had ACT >20, and in the previous year 53.5% (n=23) took OCS, 83.7% (n=36) had exacerbations requiring OCS and 37.2% (n=16) required at least one hospitalisation due to an exacerbation. After treatment, the last follow-up results were 65.1% (n=28), 23.3% (n=10), 44.7% (n=17) and 5.3% (n=2), respectively.

Conclusion and relevance Immunotherapy was effective in most cases, reducing exacerbations and hospitalisations in SUA. It also allowed discontinuation of OCS therapy. The improvement in quality of life was proved with the increase in ACT score, despite its subjectivity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-142 EFFECTIVENESS AND SAFETY OF ANTI-IL-5 BIOLOGIC AGENTS IN SEVERE EOSINOPHILIC ASTHMA

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Background and importance Severe uncontrolled asthma is characterised by poor control despite treatment with inhaled glucocorticoids (IGC) and beta₂ adrenergic agonists (LABA) at high doses, and/or oral glucocorticoids (OGC). This type of asthma comprises a heterogeneous group of phenotypes treated with targeted therapy. Anti-IL-5 monoclonal antibodies (mepolizumab, reslizumab and benralizumab) are indicated in severe eosinophilic asthma (SEA).

Aim and objectives To assess the effectiveness and safety of anti-IL-5 biologic agents in a tertiary level hospital.

Material and methods This retrospective observational study included patients with SEA receiving treatment with anti-IL-5 agents from June 2017 to August 2019. Electronic clinical records were used to obtain sociodemographic variables (age, sex, concomitant medicines and previous biologicals), effectiveness (reduction in eosinophil blood levels, change in levels of exhaled nitric oxide (FeNO), forced expiratory volume in 1 s (FEV₁) and score in the asthma control test (ACT)) and safety (reported adverse effects).

Results Thirty-four patients were included, 67.6% (23) women, and mean age was 56.2 (41–69) years. Twenty patients received mepolizumab with an average duration of 40 weeks, 4 reslizumab for 27.7 weeks and 9 benralizumab for