EFFECTIVENESS AND SAFETY OF USTEKINUMAB IN CLINICAL PRACTICE FOR CROHN’S DISEASE

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Material and methods This was a retrospective observational study, in two regional hospitals, in patients with CD who received an induction dose of ustekinumab between January 2018 and September 2019, inclusive. The data were obtained from the PRISMA-APD outpatient care programme, and by reviewing medical records in Diraya. To assess efficacy, the Harvey–Bradshaw index (HBI) was considered, for which the following variables were recorded: general condition of the patient, abdominal pain, number of daily liquid bowel movements, presence or absence of abdominal mass and other associated symptoms. Remission of the disease was considered if HBI was 1–6. Other clinical variables included were: age, sex, previous treatments with anti-TNF, concomitant use with immunomodulators and/or corticosteroids, need for intensification and treatment interruption. To assess safety, adverse effects associated with ustekinumab were considered.

Results Thirty-seven patients were included in the study: 21 women and 16 men. Median age was 45 years. With the exception of three patients, all had received prior therapy with one or more anti-TNF. Twenty of the patients had received concomitant corticosteroid and immunosuppressive medication. In 4 patients ustekinumab was withdrawn due to lack of action but 29 patients presented an HBI <6, of whom 23 had an intensified pattern (90 mg every 8 weeks). The only adverse reaction recorded was atypical erythema nodosum in a patient.

Conclusion and relevance Ustekinumab seemed to have good efficacy in CD with an intensified regimen, as the disease was in remission (HBI 1–6 points) in most patients. Its safety profile was optimum as only one patient experienced an adverse reaction and withdrawal of the drug was not necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-060 ALEMTUZUMAB FOR RELAPSING–REMITTING MULTIPLE SCLEROSIS: EFFECTIVENESS AND SAFETY


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Background and importance Alemtuzumab is a humanised monoclonal antibody that selectively targets CD52, indicated in adult patients with relapsing–remitting multiple sclerosis (RRMS).

Aim and objectives To assess the effectiveness and safety of alemtuzumab for RRMS in the clinical setting.

Material and methods A retrospective observational study of all patients with RRMS treated with at least one course of alemtuzumab from July 2016 to March 2019 was carried out. The drug was administered by intravenous infusion on 5 consecutive days at baseline and on 3 consecutive days 12 months later. All patients received prophylaxis with methylprednisolone, antihistamines, antipyretics and acyclovir.

Alemtuzumab was started in adults with active disease, defined by clinical or imaging features despite the use of immunomodulating therapies, or having a fast and aggressive course. The variables studied were sex, age, time from diagnosis, expanded disability status scale (EDSS), previous treatment, number of cycles, adverse events (AE) and number of relapses.
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post-treatment (NRPT). Data were collected from medical records and the electronic prescription program. Effectiveness was evaluated in terms of NRPT with alemtuzumab. Safety was assessed by reported treatment of AE.

Results Eleven patients, 63.6% women, mean age 38 (24–54) years, were included. Median time from RRMS diagnosis was 10 (4–20) years and mean baseline EDSS was 3.5 (2–5.5).

Patients were previously treated with a median of 3 (2–4) drugs: interferon-beta-1a (IFNβ-1a) intramuscularly (45.5%), IFNβ-1a subcutaneously (27.3%), glatiramer acetate (27.3%), natalizumab (90.9%), fingolimod (27.3%) and dimethyl fumarate (18.2%). Seven patients completed two courses of alemtuzumab, and the second course is pending in three patients. One administration was suspended due to an infusion related reaction (IRR), requiring intensive care. The mean relapse rate was 0.36 (0–2). All patients experienced IRRs: lymphopenia (63.6%) and skin disorders (72.7%). Most were mild and limited in time, except for one patient with skin rash, pruritus and oedema, requiring discontinuation of treatment. Other AE were urinary tract infection (18.2%) and herpes zoster infections (9.1%).

Conclusion and relevance According to our results, alemtuzumab was effective in clinical practice due to a low relapse rate. However, further studies with a larger number of patients are needed to confirm these results. IRRs were frequent. Nevertheless, AE were mild and well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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