became available as a unique option for oral MS treatment in our hospital in 2017.

**Aim and objectives** To describe our experience with the use of TRF and assess its safety profile, as disease modifying therapies (DMTs) work differently and have different adverse reactions (AR).

**Material and methods** An observational retrospective study was conducted from January 2017 to January 2020. Collected variables from medical records were: age, sex, expanded disability status scale score (EDSS), previous DMTs, safety profile (AR, suspension of TRF treatment) and results of blood tests. Sustained disability progression was defined as at least a 1 point increase from the baseline EDSS score ≤ 5.5 (or at least a 0.5 point increase for those with a baseline EDSS score > 5.5) sustained for at least 12 weeks.

**Results** 45 patients were analysed, 10 men and 35 women (mean age 35.7 years). TRF was the firstline drug for 10 patients, the rest had switched to TRF from parenteral therapies: 7 subcutaneous glatiramer acetate, 20 intramuscular or subcutaneous interferon beta and 2 intravenous natalizumab. The main reasons for change were: convenience of oral administration, poor tolerance and AR at the site of injection. The average duration for TRF was 2.5 years with no suspension recorded. In this period, for 30 patients EDSS score remained stable. The mean change in EDSS from baseline was 0.7; no increase in disability progression. 30 patients showed no AR and 15 patients presented gastrointestinal disorders (9), temporary alopecia (4) or headache (2). 9 patients experienced moderate elevation of liver enzymes.

**Conclusion and relevance** TRF seemed to have a manageable safety profile, was well tolerated, and no new or unexpected AR were reported and there were no suspensions of treatment. Because our experience reflects only 3 years, increased monitoring is necessary to assess the long term safety.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
1. AUBAGIO (package insert), Cambridge, MA: Genzyme Corporation

Conflict of interest No conflict of interest

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### Abstract 4CPS-309 Table 1

<table>
<thead>
<tr>
<th>Subscale</th>
<th>No of Items</th>
<th>Mean</th>
<th>Range</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMF barriers</td>
<td>13</td>
<td>2.181</td>
<td>0-39</td>
<td>63% of patients reported no barriers (score 0)</td>
</tr>
<tr>
<td>DMF side effects</td>
<td>10</td>
<td>9.302</td>
<td>0-40</td>
<td>Only 11.6% reported no SE (score 0)</td>
</tr>
<tr>
<td>DMF coping strategies</td>
<td>7</td>
<td>1.223</td>
<td>0-7</td>
<td>36.6% do not use coping strategies</td>
</tr>
</tbody>
</table>

1. Most common barriers, for 22 patients, were forgetting to administer DMT (58%), not “in the mood” to take DMT (22%) and feeling tired of taking DMT (16%).

2. 88.4% of patients reported SE such as injection phobia, injection site reaction and tolerability concerns.

3. Of 15 patients reported SE but no coping strategies in place, maybe because they were not aware of them.

### Abstract 4CPS-310

**Tofacitinib Effectiveness and Safety Results: Real World Data**

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**Background and importance** Tofacitinib is an oral JAK inhibitor indicated for the treatment of rheumatoid arthritis, psoriasis arthritis and ulcerative colitis. The efficacy and safety of tofacitinib have been shown in several randomised clinical trials.

**Aim and objectives** To evaluate the effectiveness and safety of tofacitinib in all indications used in a real world cohort of patients in a third level hospital.

**Material and methods** This was a retrospective observational study of patients who received tofacitinib from 2017 to March 2020. Demographic, clinical characteristics at baseline and outcomes analysed were: age, sex, diagnosis, number of days treated with tofacitinib, previous lines of treatment, objective response and adverse effects.
Results 30 patients were treated with tofacitinib from 2017 to March 2020, 23 women and 7 men, with a median age of 55 (48–62) years; 40% of patients were overweight. 23 patients were diagnosed with rheumatoid arthritis, 3 patients with psoriasis arthritis, 1 patient with vitiligo, 1 patient with alopecia areata and 1 patient with polyarthritis. 50% of patients were pre-exposed to methotrexate, leflunomide and/or hydroxychloroquine. Median time to stop tofacitinib was 307 (114–557) days. Reasons for stopping tofacitinib were: insufficient response (n=9), infection (n=1), headache (n=3), haematemesis (n=1) and pregnancy (n=1). 15 patients have continued treatment with tofacitinib with a good response. Elevation of liver enzymes, or changes in the levels of lymphocytes, neutrophils and haemoglobin have not been detected in any patient. 30% of patients had adverse events; more frequent adverse events were infections in 13% of patients and headache in 13% of patients.

Conclusion and relevance The efficacy and safety of tofacitinib have been demonstrated in clinical trials. This retrospective analysis of real life data showed that tofacitinib was also effective and safe in a real life setting but only 50% of the patient cohort achieved a response with a dose of tofacitinib 5 mg twice daily. Due to the size of the group, these results should be interpreted with caution; future analysis in clinical practice is necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Background and importance Chimeric antigen receptor-T (CAR-T) has demonstrated clinical efficacy in haematologic malignancies but it also has a relevant toxic side effect profile. Aim and objectives To describe the toxicity and management of CAR-T cell therapies (CARTs) (tisagenlecleucel (Tisa-cel) and axicabtagene ciloleucel (Axi-cel)) in a real world population with haematological malignancies. Material and methods A retrospective study was conducted in all patients treated with CARTs in our hospital (August 2019 to September 2020). Data collected included age, gender, diagnosis, hospital stay, admission to the intensive care unit (ICU), length of ICU stay and the main adverse events (AE) detected (cytokine release syndrome (CRS), neurological toxicity, hypogammaglobulinemia, febrile neutropenia and infections) and need for tocilizumab and/or corticosteroids to treat AE. Statistical analysis was performed using SPSS V.21.0.

Results 32 patients were included (53.1% men). Axi-cel was administered to 53.1% of patients, of whom 70.6% had diffuse large B-cell lymphoma (DLBCL) and the remaining had primary mediastinal large B-cell lymphoma (PMBCL). The rest were treated with Tisa-cel; 60.0% had DLBCL and the others had B-cell precursor acute lymphoblastic leukaemia (ALL). Median age in the ALL population was 9 years (6–14) and mean age in patients with DLBCL and PMBCL was 57.7 years (±8.8). Median hospital stay was 15 days (13–21). Two patients died during admission and one remained admitted at the data cut-off date. 15.6% required admission to the ICU and mean stay was 7 days (±6.1). Two patients presented with mild hypersensitivity reaction during CAR-T cell infusion. 81.3% presented CRS and neurological toxicity occurred in 37.5%. During admission, 78.1% presented with febrile neutropenia and 15.6% had active infections. Hypogammaglobulinemia was observed in three patients. Tocilizumab and corticosteroids were administered in 21.9% of patients in both cases. CRS and febrile neutropenia rates were similar in patients treated with Tisa-cel and Axi-cel (73.7% vs 88.2% and 80.0% vs 76.5%, respectively). Neurological toxicity was more frequent with Axi-cel (52.9% vs 20%).

Conclusion and relevance CAR-T cell therapy was generally well tolerated with a low rate of severe or life threatening AE. CRS was the most frequent AE and no differences were found between Axi-cel and Tisa-cel. Neurological toxicity rates were similar to those observed in clinical trials with Tisa-cel and lower than with Axi-cel. The need for tocilizumab and/or corticosteroids in Axi-cel patients was lower than in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest