patients, was used to determine methotrexate (MTX) intolerance prevalence in RA patients. The MISS consisted of four domains: abdominal pain, nausea, vomiting, and behavioral symptoms, occurring before (anticipatory), after, and when thinking of MTX (associative). MTX intolerance was defined as six or more points on the MISS. Our statistical analysis was based on a descriptive study and logistic regression with SPSS20.

Results: We included 102 RA patients with a mean age of 51.60 ± 14.33 years. Women were predominant (93.1%). The mean disease duration was 14.86 ± 9.78 years, with a mean methotrexate use duration of 7.42 ± 6.44 years. The mean dose of methotrexate was 12.13 ± 9.06 mg per week. The prevalence of methotrexate intolerance was 55.9%, and seventy-six patients (74.5%) experienced at least one gastrointestinal symptom during MTX treatment. After MTX administration, the most prevalent gastrointestinal symptom was nausea (93% of the intolerant patient), whereas abdominal pain occurred in 73.7% and vomiting in 57.9%. These symptoms were also prevalent before and when thinking of MTX. Anticipatory vomiting was the least prevalent, affecting 8.8%. Behavioral symptoms affected 87.7% of intolerant patients, with restlessness being the most prominent symptom in 71.9% of them. Among the intolerant patients, 45 patients (79%) took parenteral MTX, and 12 (21.1%) took methotrexate orally. In comparison, young patients (49.11 ± 14.95 years) were more intolerant to MTX than old (54.76 ± 13 years, p = 0.048) ones. However, in univariate logistic regression analysis, we did not find any significant association between methotrexate administration route, dose, duration, and digestive intolerance.

Conclusion: Methotrexate intolerance was highly prevalent in our RA population. These results strengthen the idea that early detection of MTX intolerance may avoid effective treatment discontinuation, especially in younger patients.

REFERENCES:

Disclosure of Interest: None declared.

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AB0275

TOFACITINIB EFFECTIVENESS IN PATIENTS WITH RHEUMATOID ARTHRITIS AFTER CONVENTIONAL OR BIOLOGICAL THERAPY - IT REAL ROLE IN DIFFERENT LINES OF TREATMENT

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Background: rheumatoid arthritis (RA) is a chronic and disabling autoimmune disease, with a high biologic and economic burden. This implies the need to investigate therapies that maximize clinical results. Tofacitinib is recommended as a different alternative with a high biologic and clinical efficacy. Patients with RA tolerates well the intolerant patient), whereas abdominal pain occurred in 73.7% and vomiting in 57.9%. These symptoms were also prevalent before and when thinking of MTX. Anticipatory vomiting was the least prevalent, affecting 8.8%. Behavioral symptoms affected 87.7% of intolerant patients, with restlessness being the most prominent symptom in 71.9% of them. Among the intolerant patients, 45 patients (79%) took parenteral MTX, and 12 (21.1%) took methotrexate orally. In comparison, young patients (49.11 ± 14.95 years) were more intolerant to MTX than old (54.76 ± 13 years, p = 0.048) ones. However, in univariate logistic regression analysis, we did not find any significant association between methotrexate administration route, dose, duration, and digestive intolerance.

Conclusion: Methotrexate intolerance was highly prevalent in our RA population. These results strengthen the idea that early detection of MTX intolerance may avoid effective treatment discontinuation, especially in younger patients.

REFERENCES:

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AB0276

HOW FAST CAN METHOTREXATE BE ESCALATED IN RHEUMATOID ARTHRITIS? A MULTICENTRE, PARALLEL-GROUP RANDOMIZED CONTROLLED TRIAL (MEIRA)


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Background: Literature regarding the optimal dose escalation strategy of methotrexate (MTX) in RA is scant and ambiguous (1). Concerns regarding the safety of rapid escalation may lead to delayed attainment of the optimal dose and treatment target.

Objectives: To compare the efficacy, safety and tolerability of fast versus usual dose escalation of oral MTX in RA.

Methods: This multicenter, open-label (assessor blinded) RCT included patients with active RA (SJC2 and TJC4 >18 and ≤55 years, not on DMARDs (except HCQ and/or low-dose prednisolone) and with disease duration ≤5 years. Patients were randomized 1:1 into two groups with the same starting dose of oral MTX (15mg/wk), but escalated either by 5mg every 2 weeks (fast escalation group) or 5mg every 4 weeks (usual escalation group), till a maximum of 25mg/wk.

Primary outcome was proportion of EULAR good responders at 16 weeks. Secondary outcomes were change in DAS28 at 16 weeks, disease activity at 3 months was a major factor related to 6-month response (OR 13.4, 95% CI 4.5-39.4, p value 0.000), while non-response at 3 months were associated with no response at 6 months of follow-up. Baseline DAS28 was significantly associated with response at 12 months (OR 1.9, 95% CI 1.1-3.25, p-value 0.028). At 12 months of treatment, both groups showed disease response and control according to the DAS28 from baseline, but a higher proportion of T1 patients achieved remission (45% vs 23%). A subgroup analysis to evaluate T2 second-line Tofacitinib therapy showed no statistically significant differences in any response criteria according to the number of previously received biologics.

Table 1. Regression analysis (risk of response of the disease at 6 and 12 months of treatment with Tofacitinib)

<table>
<thead>
<tr>
<th>Factor Response at Month 6</th>
<th>OR</th>
<th>IC95%</th>
<th>P value</th>
<th>OR</th>
<th>IC95%</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1.00</td>
<td>0.97-1.03</td>
<td>0.788</td>
<td>1.02</td>
<td>0.98-1.06</td>
<td>0.211</td>
</tr>
<tr>
<td>Age</td>
<td>1.82</td>
<td>0.65-5.08</td>
<td>0.251</td>
<td>0.81</td>
<td>0.27-2.38</td>
<td>0.709</td>
</tr>
<tr>
<td>Duration of RA</td>
<td>0.99</td>
<td>0.94-1.04</td>
<td>0.908</td>
<td>1.02</td>
<td>0.96-1.08</td>
<td>0.444</td>
</tr>
<tr>
<td>Positive Rheumatoid Factor</td>
<td>0.81</td>
<td>0.02-0.56</td>
<td>0.730</td>
<td>0.63</td>
<td>0.17-2.26</td>
<td>0.485</td>
</tr>
<tr>
<td>Positive Anti-CCP</td>
<td>0.34</td>
<td>0.06-1.60</td>
<td>0.169</td>
<td>0.37</td>
<td>0.01-2.82</td>
<td>0.039</td>
</tr>
<tr>
<td>Initial DAS28</td>
<td>1.61</td>
<td>1.04-2.49</td>
<td>0.033</td>
<td>0.67</td>
<td>0.13-3.53</td>
<td>0.018</td>
</tr>
<tr>
<td>First line</td>
<td>0.44</td>
<td>0.19-1.01</td>
<td>0.054</td>
<td>1.47</td>
<td>0.56-3.83</td>
<td>0.423</td>
</tr>
<tr>
<td>Treatment period</td>
<td>1.12</td>
<td>0.80-1.55</td>
<td>0.392</td>
<td>0.73</td>
<td>0.47-1.16</td>
<td>0.107</td>
</tr>
<tr>
<td>Dose: 11mg</td>
<td>0.95</td>
<td>0.42-2.13</td>
<td>0.904</td>
<td>0.75</td>
<td>0.29-1.85</td>
<td>0.565</td>
</tr>
<tr>
<td>Response at Month 3</td>
<td>13.42</td>
<td>4.57-39.4</td>
<td>0.000</td>
<td>2.32</td>
<td>0.87-6.18</td>
<td>0.091</td>
</tr>
</tbody>
</table>

*p=0.9* or DAS28-3 at 24 weeks was compared.

Conclusion: Tofacitinib is an effective treatment option for patients with RA after conventional DMARDs and in patients after biologic therapy failure, but maybe is better used as a T1 first-line of treatment. Further studies are required to determine the real role of tofacitinib in different lines of RA treatment.

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*Positive Anti-CCP at month 12 was omitted because of collinearity*