“REAL WORLD” EXPERIENCE OF TOFACITINIB AND BARICITINIB IN THE TREATMENT OF RHEUMATOID ARTHRITIS: EFFECTIVENESS AND SAFETY EVALUATION

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Purpose

Tofacitinib and baricitinib are approved for rheumatoid arthritis (RA) treatment. In pivotal clinical trials patients had higher DAS28-ESR than our patients and were less pre-treated with biologic Disease Modifying Antirheumatic Drugs (bDMARDs).

To assess effectiveness and safety of JKi in patients with RA in clinical setting.

Results

53 patients
Mean age: 63.9 ± 13.3 years
46 (86.8%) women.

**Remission** (DAS28-ESR<2.6)
- Tofacitinib (ToF): n= 44
  - 83.0%
- Baricitinib (BarG): n= 9
  - 17.0%

**Low disease activity** (2.6<DAS28-ESR<3.2)

**Moderate disease activity** (3.2<DAS28-ESR<5.1)

**High disease activity** (DAS28-ESR>5.1)

Discontinued JKi
- Baricitinib (n= 3; 33.3 %)
- Tofacitinib (n= 9; 20.5 %)

At beginning of study...
Remission: n= 1
(1.9 %)
Mean DAS28-ESR: 4.97 ± 1.32

During monitoring period...
Remission: n= 9
(17.0 %)
Mean DAS28-ESR decrease: 0.69 ± 1.44 (10.3 ± 30.8 %), p<0.001

Mean DAS28-ESR for each treatment after switching:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mean DAS28-ESR (±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tofacitinib</td>
<td>4.64 ± 1.44 (9.3 ± 32.0 %)</td>
</tr>
<tr>
<td>Baricitinib</td>
<td>0.98 ± 1.44 (15.6 ± 23.0 %)</td>
</tr>
</tbody>
</table>

Reasons of discontinuation:

<table>
<thead>
<tr>
<th>JKi</th>
<th>Lack of effectiveness</th>
<th>Lack of adherence</th>
<th>Adverse effects</th>
<th>Patient’s choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baricitinib</td>
<td>n= 2; 22.2 %</td>
<td>n= 1; 11.1 %</td>
<td>n= 0; 0 %</td>
<td>n= 0; 0 %</td>
</tr>
<tr>
<td>Tofacitinib</td>
<td>n= 5; 9.4 %</td>
<td>n= 2; 3.8 %</td>
<td>n= 1; 1.9 % (oedema, dyspnoea)</td>
<td>n= 1; 1.9 %</td>
</tr>
</tbody>
</table>

Material and Methods

Observational retrospective study: 2016-2019

Patients with RA > 18 years old

"Patient and treatments registry program" of our local government

"Clinical disease impact (analized variables)"
- Demographic, indication, previous and current treatments, discontinuity of treatment and reasons, effectiveness and safety data.
- Disease activity score DAS28-ESR
  - Baseline and during follow up of JKi treatment

**Previous non-biologic disease modifying antirheumatic drugs (non-bDMARDs) treatments**
- Methotrexate n= 39 73.6 %
- Lefunomide n= 34 64.2 %
- Hydroxychloroquine n= 15 28.3 %
- Sulfasalazine n= 9 17.0 %

**Previous biologic disease modifying antirheumatic drugs (bDMARDs) treatments**
- ToF: 0 - 3 n= 22 50.0 %
- BarG: > 3 n=15 34.1 %
- ToF: n= 2 22.2 %
- BarG: n= 4 44.4 %

**Conclusion**

Our study suggests that JKi could be effective in real-world settings after switching from other multiple bDMARDs.

Results showed a modest benefit of JKi in complicated and over treated patients with diverse backgrounds, as found in daily practice.