CASE-CONTROL TRIAL OF HAKKA PEOPLE IN SOUTHERN CHINA

Objectives: Hakka people have the purest genes of the majority people-Han in China. It is planned to recruit 160 RA patients in Meizhou, where is a gathering place of Hakka people.

Methods: The RA volunteers had no relief with 10mg/w oral dose of MTX with/without other 1-2 inadequate dose of DMARDs for at least 3 months. They were randomly divided into 1:1 groups. The experimental group would be treated with original DMARDs and incremental MTX (gradually increased to the optimal dose) with/without other 1-2 inadequate dose of DMARDs. While the control group would be treated with original MTX dose(10mg/w) or other 1-2 inadequate dose of DMARDs for at least 3 months.

Results: 1) We planned to recruit 160 RA patients in our study. 46 Hakka RA patients were enrolled in the study so far. 2 of 46 finished the 24th week visit and 24 finished the 36th week visit. The average age is 54.2±9.3 years old, the average age weight is 59.1±11.1kg, and the female to male ratio is 41:5. 2) The average Folic acid dose is 14.4±9.5mg/w in the experimental group at the 12th week.

Conclusion: Hakka patients in China might have better outcomes due to increasing MTX to the 0.3mg/kg/w dose than increasing the other DMARDs. The appropriate dose of Folic acid plus with the optimal dose of MTX in our study is higher than previous studies (such as 13.0±4.8mg/w reported by Gaujoux-Viala, 2018[1]). We recommended Chinese patients take 15mg/w folic acid to prevent MTX side effects in view of lower folic acid level in Chinese population.[3]

References:

Disclosure of Interests: None declared
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AB0347
INCREASING TO OPTIMAL METHOTREXATE DOSE MIGHT BE A BETTER TRADITIONAL DMARD STRATEGY IN RA TREATMENTS: A RANDOMIZED CASE-CONTROL TRIAL OF HAKKA PEOPLE IN SOUTHERN CHINA

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Background: The optimal methotrexate (MTX) dose is defined as 0.3mg/kg/week or ≥20mg/week in 6 months. [1] Considering average weight of Chinese, [2] the optimal MTX should be >15mg/w. However, not more than 30% in 25191 RA cases ever had MTX treatment in CREDIT (Chinese Registry of Rheumatoid arthritis). [3] The biggest concern is side effects of MTX. Our study is to investigate whether increasing MTX would get better results accompanied with more side effects to Chinese people.

Objectives: Hakka people have the purest genes of the majority people-Han in China. It is planned to recruit 160 RA patients in Meizhou, where is a gathering place of Hakka people.

Methods: The RA volunteers had no relief with 10mg/w oral dose of MTX with/without other 1-2 inadequate dose of DMARDs for at least 3 months. They were randomly divided into 1:1 groups. The experimental group would be treated with original DMARDs and incremental MTX (gradually increased to the optimal dose (0.3mg/kg/w) in the first 12 weeks and folic acid (the dose adjusted on demand with range from 5mg/w to 5mg tid). While the control group would be treated with original MTX dose(10mg/w) but incremental original DMARDs (gradually increased to the maximum dose in the first 12 weeks). The two groups would keep the treatment at 12th week last to the 36th week, and the efficacy and safety indexes would be evaluated during the whole study.

Results: 1) We planned to recruit 160 RA patients in our study. 46 Hakka RA patients were enrolled in the study so far. 2 of 46 finished the 24th week visit and 24 finished the 36th week visit. The average age is 54.2±9.3 years old, the average age weight is 59.1±11.1kg, and the female to male ratio is 41:5. 2) The average Folic acid dose is 14.4±9.5mg/w in the experimental group at the 12th week.

Conclusion: Hakka patients in China might have better outcomes due to increasing MTX to the 0.3mg/kg/w dose than increasing the other DMARDs. The appropriate dose of Folic acid plus with the optimal dose of MTX in our study is higher than previous studies (such as 13.0±4.8mg/w reported by Gaujoux-Viala, 2018[1]). We recommended Chinese patients take 15mg/w folic acid to prevent MTX side effects in view of lower folic acid level in Chinese population.[3]
Conclusion: In this study, we demonstrated the short-term effectiveness and safety profiles of baricitinib after insufficient response to bDMARDs or tsDMARDs in patients with RA in the ‘real-world’ setting. Baricitinib improved disease activity after failure of the previous agent, even after IF to another tsDMARD. With respect to safety, the profile is almost tolerable, although careful observation is necessary for possible complications and AEs including herpes zoster.


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**AB0349** EFFICACY OF TOFACITINIB THERAPY, DEPENDING ON THE USE OF DMARDS IN PATIENTS WITH RHEUMATOID ARTHRITIS IN A REAL CLINICAL PRACTICE IN RUSSIAN FEDERATION.

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Background: Objectives: To evaluate how disease-modifying antirheumatic drugs (DMARDs) affects efficacy of tofacitinib (TOFA) therapy in patients with rheumatoid arthritis (RA).

Methods: We analyzed the history of 107 patients (mean age 51.4±12.1 yrs) with RA according to the 2010 ACR/EULAR criteria, from 11 regions Russian Federation, including patients who were treated at the V.A. Nasonova Research Institute of Rheumatology. These patients were non-responders to DMARDs, previously biologic therapy and were treated with TOFA in combination with DMARDs or without. 107 patients (77 woman (72%), tested positive for ACCP (76.5%) and PIP (87.3%), the median disease duration was 7.5±6.8 years; the mean DAS28 score was 5.8±1.0, mean SDAI and CDAI score was 35.6±13.4 and 32.1±12.4 respectively) received TOFA for 12 months. TOFA therapy was started in all patients in dose 5mg BID per os with escalation to 10mg BID in 17.6% pts.

Results: The use of TOFA was accompanied by a decrease in the disease activity after 6 and 12 months of therapy. All patients were divided into 3 groups, depending on DMARDs therapy: TOFA+ methotrexate (MTX), TOFA+ another DMARDs (leflunomide, hydroxychloroquine, azathioprine), mono-therapy of TOFA. The dynamic of the disease activity in 3 groups is presenting on the table below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Weeks</th>
<th>TOFA+MTX</th>
<th>TOFA+another DMARDs</th>
<th>TOFA mono-thrapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAS28 (ESR)</td>
<td>baseline</td>
<td>5.9±1.0</td>
<td>5.6±1.1</td>
<td>6.0±0.8</td>
</tr>
<tr>
<td>6 months</td>
<td>3.5±1.2*</td>
<td>4.1±1.1*</td>
<td>4.2±1.6*</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>3.3±1.0*</td>
<td>3.5±1.3*</td>
<td>3.8±1.2*</td>
<td></td>
</tr>
<tr>
<td>SDAI</td>
<td>baseline</td>
<td>36.2±14.2</td>
<td>32.6±9.5</td>
<td>35.8±10.3</td>
</tr>
<tr>
<td>6 months</td>
<td>14.4±10.7*</td>
<td>16.7±10.2*</td>
<td>27.3±19.1*</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>9.8±8.0*</td>
<td>12.8±8.6*</td>
<td>16.3±10.2*</td>
<td></td>
</tr>
<tr>
<td>CDAI</td>
<td>baseline</td>
<td>32.4±12.1</td>
<td>29.7±8.9</td>
<td>33.2±9.8</td>
</tr>
<tr>
<td>6 months</td>
<td>13.3±10.2*</td>
<td>15.6±8.8*</td>
<td>22.4±16.8*</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>8.7±7.6*</td>
<td>12.6±8.2*</td>
<td>14.4±9.6*</td>
<td></td>
</tr>
</tbody>
</table>

*p<0.05

Patients who received TOFA with MTX had lower disease activity during the therapy. Patients on mono-therapy of TOFA had higher disease activity according to DAS28, SDAI, CDAI.

Conclusion: Tofacitinib is effective ts-DMARDs for active rheumatoid arthritis on the Russian population. It shows better efficacy in combination with methotrexate, than in combination with another DMARDs (leflunomide and other) or in mono-therapy.

Disclosure of Interests: None declared

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**AB0350** EFFICACY OF ADDING IGURATIMOD THERAPY IN RHEUMATOID ARTHRITIS PATIENTS WHO HAD INADEQUATE RESPONSE TO BIOLOGIC DMARDS TO RA IN ELDERLY PATIENTS

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Background: Iguratimod (IGU) was newly approved in Japan in June 2012 and recommended by JCR guideline 2014 in the treatment of rheumatoid arthritis (RA). Although there have been efficacy of monotherapy and concomitant MTX in clinical trials, however, there have been no reports of concomitant biologic DMARDs (Bio).

Objectives: we investigated efficacy of concomitant IGU therapy in RA patients who had inadequate response to Bio at the author's institution.

Methods: Subjects were 107 patients adding IGU who had inadequate response to Bio from January 2014 to October 2018. Previous treatment Bio. was ADA. And baseline mean concomitant MTX was 12.3mg/wk. And baseline characteristics were Mean age 53.8 years, mean duration of illness 5.5 years, corticosteroid use 9.3%(mean 3.1mg/day). The course of DAS28, SDAI, CDAI and remission rates were analyzed.

Results: Mean DAS28-ESR, SDAI, CDAI were significantly decreased from the initiation of IGU treatment at 24 weeks (3.1→2.3, 7.1→2.6, 7.5→2.4), at 52 weeks (2.1, 2.4, 2.0). Remission rates of DAS28-ESR, SDAI, CDAI were 69.2%, 70.1% at 24 weeks, 74.8%, 78.5%, 79.4% at 52 weeks. There were no side-effect that must be stopped after adding IGU.

Conclusion: IGU might be a new RA treatment option for aiming remission in patients who had inadequate response to Bio.

References:


Disclosure of Interests: None declared

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**AB0351** EFFICACY OF IGURATIMOD FOR RHEUMATOID ARTHRITIS IN ELDERLY PATIENTS

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Background: Iguratimod (IGU) was started development as new non-steroidal anti-inflammatory drugs (NSAIDs), but it was changed for development as disease modifying antirheumatic drugs (DMARDs) because it showed suppression of inflammatory cytokine and inflammatory parameter which was not to be found in existing NSAIDs in the early stage of pharmacological study of drug efficacy. Although the clinical efficacy and the safety of IGU were already reported, the efficacy for elderly cases was not sufficiently analyzed.