forward (LOCF) was used for continuous endpoints and binary endpoints after Wk26. Treatment-emergent adverse events (AE) per 100 pt yrs (PY) were summarized up to July 6 2018 for pts with any exposure to ADA or UPA.

**Results:** In SELECT-COMPARE, 1629 pts were randomized at BL. Among 651 pts randomized to UPA, 38.7% were rescued between Wks 14-26; of those who remained on UPA, 86% completed Wk 48, while 5.8% and 0.3% discontinued study drug between BL and Wk 48 due to AE and lack of efficacy (LoE), respectively. Among 327 pts randomized to ADA, 48.6% were rescued between Wks 14-26; of those who remained on ADA, 76% completed Wk48, while 13.1% and 0 discontinued study drug between BL and Wk 48 due to AE and LoE, respectively. The cumulative exposures were 1243.3 and 467.8 PYs for UPA and ADA, respectively. At Wk 26, and Wk 48, significantly more pts in the UPA vs ADA group achieved ACR20/50/70, low disease activity and remission (Table 1); this was true for visits between Wks 26 and 48. Similarly, improvements in pain and function were significantly greater in the UPA vs ADA group through Wk48. At Wk 26, there was significantly less radiographic progression for UPA vs PBO, which was maintained through Wk48 (based on linear extrapolation). Adverse events are reported in Table 2 (in events per 100 PY). The rate of AE leading to discontinuation was higher with “any ADA” vs “any UPA”, while the rate of Herpes zoster was higher with “any UPA” exposure. Inhibition of structural joint damage after Wk26. Treatment-emergent adverse events (AE) per 100 pt yrs (PY) were summarized up to July 6 2018 for pts with any exposure to ADA or UPA.

**Conclusion:** UPA continued to demonstrate superior clinical and functional responses vs ADA through Wk48. Inhibition of structural joint damage for UPA continued to demonstrate superior clinical and functional responses vs ADA through Wk48. Inhibition of structural joint damage for UPA vs PBO, which was maintained through Wk48 (based on linear extrapolation). Adverse events are reported in Table 2 (in events per 100 PY). The rate of AE leading to discontinuation was higher with “any ADA” vs “any UPA”, while the rate of Herpes zoster was higher with “any UPA” exposure.

**REFERENCES:**


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**FRI0148**

**IS TREATMENT ADHERENCE OF RA PATIENTS TO MTX IMPROVED BY THE SWITCH FROM ORAL TO SUBCUTANEOUS ADMINISTRATION? RESULTS FROM THE PROSPECTIVE APRIM STUDY**

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**Background:** Previous studies have shown, that switching from oral to SC MTX can lead to improved efficacy and bioavailability (especially for doses ≥15mg/wk) as well as to a decreased frequency of adverse gastrointestinal effects in patients with RA. Furthermore, some reports consider that this switch may improve treatments adherence and persistence.

**Objectives:** The purpose of APRIM study was to investigate the treatment adherence of RA patients switching from oral to injectable MTX or between two different MTX prefilled syringes.

**Methods:** APRIM is a prospective, observational, multicentre study, which included adult patients with confirmed RA diagnosis (ACR/EULAR 2010 criteria) already treated by either oral MTX and requiring route modification (Gr1), or SC MTX in prefilled syringe (PFS) and eligible for a device switch (to another PFS) (Gr2). The primary criterion of the study was to estimate at 6 months the proportion of patients with strong or improved at least 1 category treatment adherence evaluated by Morisky’s self-assessment (8: strong maximum adherence, 6-7: medium adherence, <6: poor adherence) in both groups.

**Results:** Between June 2016 and June 2017, 110 rheumatologists, at 90% with private practice, included 466 pts, 433 of which composed the analysable baseline set. Pts baseline characteristics Gr1/Gr2 were [mean (SD)]; age: 59.2 (13.0)/61.5 (12.2) yrs; RA duration: 6.5 (7.9)/9.9 (10.5) yrs; MTX use duration: 3.6 (4.6)/6.0 (5.1) yrs; DAS28: 3.9 (0.9)/3.2 (1.2); Erosive RA: 37%/53%. All pts were receiving MTX at a mean (SD) dose of at least 1 category for respectively 56% and 60% of patients [Gr1/Gr2]. Proportion of patients with strong treatment adherence improved from 40% (0%) to 48% (6%) in both Gr1 and Gr2. Interestingly, when the rheumatologists were asked to estimate their patients’ adherence, they reported respectively 77% and 84% [Gr1/Gr2] of patients with “no missed injections”. At baseline patients in the Gr1 (oral baseline) had a higher DAS28 than in Gr2, this difference was removed after 6 months of MTX SC treatment. No new safety signals were identified during this study.

**Conclusion:** The results of the observational study APRIM revealed that less than 50% of patients are perfectly adherent to injectable MTX treatment, irrespectively of whether was their previous MTX way of administration. Though, this proportion seems to be highly overestimated by the rheumatologists. This underlies the importance of patient/physician effective communication.

**REFERENCES:**


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**Disclosure of Interests:**

Naina Barretto of AbbVie, Inc. was the study sponsor, contributed to study design, data collection, analysis & interpretation, and to writing, reviewing, and approval of final version. Medical writing support was provided by René-Marc Flipo, Eric Senberf, Sonia Tropé, Elena Zinovieva, Agnès Courbeyrette, Hélène Herman-Demars, Hôpital Roger Salengro, Rheumatology Department, Lille, France; and to writing and reviewing of scientific abstracts. Springer Healthcare Ltd was the study sponsor. No other conflicts of interest declared.
DISEASE ACTIVITY IN ESCALATION OR DE-ESCALATION OF DOSAGE OF TOFACITINIB IN RHEUMATOID ARTHRITIS PATIENTS – THE FIRST RESULTS OF RUSSIAN NATIONAL REGISTER OF PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH TOFACITINIB


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Background: In previous studies tofacitinib (TF) had demonstrated efficacy of two dosages (10 and 20 mg/day) in patients with rheumatoid arthritis (RA). However, the expected results of switching of TF dosages are unknown.

Objectives: The aim of the study was to evaluate the results of switching of TF’s dosages in RA patients.

Methods: Were analyzed the data from Russian national register of patients with RA treated with TF (tofacitinib), 415 patients were involved in the register (aug 2018). In statistical analysis were included data from patients with RA treated with TF (tofacitinib). 415 patients were involved in the register (aug 2018). In statistical analysis were included data from 41 patients with RA (EULAR 2010), who switched dosage of TF at visit 3 and had complete clinical and laboratory data from 5 consecutive visits with an interval of 3 months between the visits. Demographical (age, sex) data, disease activity data and TF dosages were evaluated. C-reactive protein level was collected, table 1. Changes in disease activity were calculated to patients with switching of the tofa’s dosage (the visit before and after the switching).

Results: 128 (68%) of patients were treated with NSAIDs, 24 (50%) with 5-10 mg of prednisolone, 34 (82.9%) with methotrexate (10-25 mg/week), biologics – 5 (4.2%).

Table 1. Baseline characteristics of the patients with RA included in the study (n=41)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>10 (24.3)</td>
</tr>
<tr>
<td>Caucasians, n (%)</td>
<td>41 (100)</td>
</tr>
<tr>
<td>Asians, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Age of disease onset, years (mean ±SD)</td>
<td>40.1±11.05</td>
</tr>
<tr>
<td>Symptoms duration, month (mean ±SD)</td>
<td>98.7±87.1</td>
</tr>
<tr>
<td>Positive rheumatoid factor, n (%)</td>
<td>32 (78)</td>
</tr>
<tr>
<td>Positive antibodies to cyclic citrullinated peptide (anti-CCP), n (%)</td>
<td>37 (90.2)</td>
</tr>
<tr>
<td>BMI, kg/m² (mean ±SD)</td>
<td>25.1±5.98</td>
</tr>
<tr>
<td>Smokers (current and in the anamnesis), n (%)</td>
<td>33 (80)</td>
</tr>
</tbody>
</table>

From 41 persons with RA 32 patients, who never achieved low disease activity (DAS28<3.2) or remission (DAS28<2.6) elevated the dosage of tofa from 10 to 20 mg/day and 9 patients with DAS28 < 3.2 decreased the dosage from 20 to 10 mg/day. After escalation of TF dosage DAS28 decreased from 5.42±1.22 to 4.22 ±1.21 (p<0.00), n=32. In 10 patients escalation lead to DAS28-remission (DAS28 <2.6) and in 12 patients - to low disease activity (DAS28<3.2).

10 patients had no clinical or laboratory response on escalation of TF dosage. Interestingly, that responders before escalation of dosage had mean DAS28 3.54 (min 3.2 – max 4.9) and non-responders – 5.54 (min 5.3-max 6.9), p<0.000.

De-escalation of the dosage from 20 to 10 mg/day was not associated with significant changes of DAS28 (1.99 ± 1.25 increased to 2.1 ±0.96 respectively, p=0.82).

Conclusion: Escalation of dosage of TF in RA lead to improvement of the disease activity in non-complete responders, who achieved DAS 28 3-5.1, but not in patients with absence of any response (DAS28 before escalation 5.3-6.9). De-escalation of TF dosage in patients with DAS28 < 2.6 dose not lead to significant changes of RA’s activity.

REFERENCES:

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