Abstract AB0499 – Table 1. Variables at baseline

VARIABLES	MTX	MTX+MTDX	p-value
Disease duration (yy), m±SD	4.91±1.70	4.69±1.80	ns
AST (U/l), m±SD	13.18±3.19	18.46±7.15	ns
ALT (U/l), m±SD	17.09±6.35	20.23±7.96	ns
VAS Pain, m±SD	23.64±19.76	27.31±20.17	ns
DAS28, m±SD	3.6±0.91	3.72±0.87	ns
HAQ, m±SD	0.61±0.47	0.68±0.37	ns
MTX (mg), m±SD	12.27±2.61	12.69±2.59	ns
GC (mg), m±SD	3.41±2.80	4.04±2.61	ns

SD: standard deviation; ns: not significant; AST: aspartate amino transaminase; ALT: alanine amino transaminase; MTX: methotrexate; MTDX: Metadoxine; GC: glucocorticoids

Abstract AB0499 – Table 2. Comparison of Hepatic Functions between two groups

LIVER ENZYMES	MTX			MTX+MTDX		
	4a wk	12a wk	Δ	4a wk	12a wk	Δ
AST(U/l), m±SD	39,09	34,82	4,27	42,46	24,08	18,38
ALT(U/l), m±SD	46,82	40,73	6,09	43,92	24,69	19,23

AST: aspartate amino transferase; ALT: alanine amino transferase; MTX: Methotrexate; MTDX: Metadoxine;

Conclusions: This study showed the possible effect of MTDX in increasing the tolerance to the MTX without affecting its effectiveness. Its role may indeed have useful implications in patients who start the therapy with MTX or in those who develop hepatic toxicity during the treatment.

REFERENCE:

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AB0500 EFFICACY AND SAFETY OF TOFACITINIB (TOF) IN PATIENTS WITH RHEUMATOID ARTHRITIS AT 52 WEEKS IN CLINICAL PRACTICE

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Objectives: There are few long-term experience of TOF for Rheumatoid arthritis (RA) patients in clinical use. We evaluated 52 and 104 weeks efficacy and safety of TOF in patients with rheumatoid arthritis in clinical practice.

Methods: We enrolled 77 RA patients started to treat with TOF between December 2013 and November 2016 in our hospital. All patients received 5 mg of TOF twice daily. We evaluated clinical disease activity in composite measures (including Disease Activity Score 28(DAS28) -Erythrocyte (-ESR), - C-reactive protein (-CRP), Simple Disease activity Index (SDAI) and Clinical Disease Activity Index (CDAI)) every three months and adverse events (AEs) during 52 and 104 weeks after treatment with TOF. We estimated the drug survival rate with Kaplan-Meier survival analysis.

Results: The mean age of patients was 66.3 years and the duration of disease was 15.4 years. Fifty-four (74.0%) patients have positive rheumatoid factor (RF) and 59 (78.7%) patients have positive anti-citrullinated protein antibodies (ACPA). Twenty-three patients were biologic-naïve and fifty-four patients have ever been treated with biologic DMARDs of whose mean number is 2.6 prior to TOF. Regarding the last biologic DMARDs: 14 patients have treat with TNF inhibitor (Infliximab, etanercept, adalimumab, golimumab, certolizumab-pegol), 30 patients with tocilizumab and 10 patients with abatacept. Twenty-three (29.9%) patients were treated with TOF without methotrexate (MTX). Disease activity at TOF start with measured with DAS28-ESR, DAS28-CRP, SDAI and CDAI were 5.15, 4.07, 23.3 and 21.5 respectively. The Drug survival rate at 24 weeks is 84.4% and that at 52 weeks is 73.8%. Twenty-seven patients have been treated with tofacitinib over 104 weeks. Twelve patients was stopped to treat within initial 24 week, including due to adverse events (n=5) and lack of efficacy (n=7). Analysed by last observation continued forward (LOCF) method, the mean of DAS-ESR decreased to 3.52 at 24 week and 3.59 at 52 week. CDAI decreased from 21.5 to 7.94 at 24 week and

7.93 at 52 week. Sixteen (20.8%) patients were remission as which defined less than 2.6 in DAS-ESR and 13 (16.9%) were low disease activity (LDA) as which defined less than 3.2 in DAS-ESR. In 23 patients without MTX, 6 (26.0%) and 5 (21.7%) have achieved remission and LDA at 52 W respectively. The adverse events due to which the patients had to be stopped to treat with TOF occurred in 20.6% of patients in initial 52 weeks. Infection was the most frequent AE to TOF, especially herpes zoster (7 patients). Six patients experienced herpes zoster within 6 month after treat with TOF. All of them could restart to treatment of TOF. Two solid tumours were discovered within 6 months after treatment, both of them had been removed by surgery and has not recurred.

Conclusions: Our study shows that TOF can be much effective clinically and have longer-lasting effectiveness. In our patients, herpes zoster was almost as frequent as reported in the phase III trials in Japan and we could retreat almost of them with TOF.

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AB0501 ADVERSE EVENTS WITH TREATMENT REGIMENS OF RHEUMATOID ARTHRITIS (RA) REPORTED BY PATIENTS APPLYING SMART SYSTEM OF DISEASE MANAGEMENT (SSDM) MOBILE TOOLS: A COHORT STUDY OF RA PATIENTS IN CHINA

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Background: Hepatic, hematologic and other adverse events (AE) during treatment in RA patients are unavoidable. And monitoring AE in long-term treatment is quite necessary as a part of chronic disease management. SSDM is a smart mobile tool to help patients upload their therapeutic regimens, lab test records and report AEs. Our previous study showed that patients in China can master the application of SSDM after training.

Objectives: To determine and compare the incidence of adverse events during treatment of RA with different therapeutic regimens, focusing on mono and combination therapy.

Methods: The SSDM includes interfaces of both physicians' and patients' application. Patients were educated to enter the data of lab test records and treatment regimens once a month, all data can be synchronised automatically to the authorised physicians' mobile tool, which formed a large patient reported database. The rheumatologists can also adjust treatment regimens base on patients' profile.

Results: From Aug 2014 to Jan 2018, a total of 7048 RA patients from 480 centres in China were entered in the cohort study. These patients contributed more than 12 600 patient-years (PY) of total followup. The mean age was 48.98 ±16.08 (18 to 99) years and the median disease duration was 23.27 months. The treatment regimens include mono or combination of leflunomide(LEF), MTX, hydroxychloroquine (HCQ), sulfasalazine(SSZ), glucocorticoid(GC), biologic DMARD, Tripterygium wilfordii, meloxicam, celecoxib, iguratimod, etc. In this database the five most common treatment regimens is LEF monotherapy (3801 PY), MTX monotherapy (1321 PY), LEF +MTX (1086 PY), HCQ monotherapy (715 PY), LEF +HCQ (576 PY). The incidence rate of hepatic events was lower for LEF monotherapy (35 events/1000 PY) than MTX (52 events/1000 PY) and LEF +MTX combination therapy (115 events/1000 PY) (p<0.01). The incidence rate of leukopenia was lower for LEF monotherapy (42 events/1000 PY) and MTX monotherapy (39 events/1000 PY) than LEF +MTX combination therapy (84 events/1000 PY) (p<0.01).

Conclusions: The findings show that mono or combination of csDMARDs are the most commonly used drugs in Chinese RA patients. And AEs may be well described in this patient report database because of the large sample sizes and empowering patient themselves. RA patients can get better safety in the long-term treatment via SSDM.

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