

Rheumatoid arthritis - non biologic treatment

AB0417 EFFICACY AND SAFETY OF METHOTREXATE AND LEFLUNOMIDE AS A COMBINATION THERAPY IN RHEUMATOID ARTHRITIS PATIENTS WITH HIGH DISEASE ACTIVITY PRESENTING AT A TERTIARY CARE SETTING IN PAKISTAN

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Background: In the management of rheumatoid arthritis (RA), the goal is remission. However it is not easy to attain this goal in all patients. Its not only the high disease activity, but rather other factors like availability and cost of biologics in developing countries. Therefore various combination therapies of conventional DMARDs are in vogue in such scenarios. Methotrexate (MTX) and Leflunomide (LEF) in combination is an effective option which can be fairly utilized in resource constraint settings to induce remission.

Objectives: To study the efficacy and safety profile of MTX+LEF combination in patients with active RA at 24 weeks.

Methods: This is a quasi-experimental study conducted at Rheumatology department, Fauji Foundation Hospital, Rawalpindi. 95 patients with active RA despite optimal dose (20–25 mg/week) of MTX. Leflunomide 20mg/day was added. Patients underwent clinical and laboratory review at 0, 4, 12 and 24 weeks to note down primary efficacy end points and adverse effects.

Results: Ninety five patients were enrolled with a mean age (years) \pm SD of 51.7 \pm 8.9 and a mean duration of disease (years) of 8.6 \pm 7.1. Patients had active disease at baseline with a mean disease activity score (DAS28) of 5.99 \pm 0.6. At 24 weeks the mean change in tender joint count (TJ), swollen joint count (SJ), patients pain score on visual analogue scale (VAS) and DAS 28 were all statistically significant (p-value 0.000). The mean change in m HAQ was also statistically significant (p-value 0.000).

At 6 months the most frequent side effects (though mostly mild); were abdominal pain and nausea. 78 patients (79.1%) continued with the combination therapy. Only 3 patients stopped the treatment temporarily (due to raised ALT and vomiting). 14 patients discontinued treatment mainly due to diarrhea, severe oral ulcers and markedly raised ALT.

Table 1. Baseline clinical and demographic feature of patients enrolled for MTX+LEF combination therapy

Total patients	95 (100%)
Age mean \pm SD (years)	51.7 \pm 8.9
Gender m/f	2/93
Duration of disease mean \pm SD (years)	8.6 \pm 7.1
RA factor (positive)	72 (75.8%)
Anti CCP (positive)	61 (64.2%)
Premorbid	
Diabetic (DM)	10 (10.5%)
Hypertensive (HTN)	16 (16.2%)
DM+HTN	3 (3.2%)

Table 2. Outcome/efficacy measure of MTX+LEF (n=95)

	Baseline (0 week)	24 weeks	p-value
Mean TJ	14.92 \pm 6.44	3.38 \pm 2.38	0.000
Mean SJ	4.29 \pm 2.30	0.90 \pm 1.28	0.000
Mean pain VAS (Patient)	7.19 \pm 1.86	2.91 \pm 1.85	0.000
Mean ESR	33.3 \pm 9.10	16.78 \pm 5.99	0.000
Mean DAS 28	5.99 \pm 0.64	3.52 \pm 0.86	0.000
Mhaq	1.75 \pm 0.64	0.59 \pm 0.42	0.000

Conclusions: MTX+LEF combination is an effective and safe option in RA patients failing MTX monotherapy provided regular clinical and laboratory monitoring is done.

Disclosure of Interest: None declared

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AB0418 COMPARISON OF ANTI-INFLAMMATORY DRUGS WITH GLUCOCORTICOID IN TREATMENT OF RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) is a chronic autoimmune disease that commonly presented with symmetrical polyarthritis of hands and feet. Pharmacological treatment options are non-steroid anti-inflammatory drugs (NSAIDs), glucocorticoids (GK) and disease modifying anti rheumatoid drugs (DMARDs) [(csDMARDs) or (tsDMARDs) or (bDMARD)].

Objectives: In this study we aimed to review the use of NSAID and GK in our patients.

Methods: The patients who diagnosed as RA at our office were included in the study. Patients were classified with EULAR 2010 RA criteria. The demographics and medications of the patients were recorded. All patients we examined pain with visual analog scale (VAS), global assessment of patient and doctor, number of tender and swollen joints (28 joints), health assessment questionnaire (HAQ),

C – reactive protein (CRP), erythrocyte sedimentation rate (ESR), rheumatoid factor (RF) and anti – CCP. We assessed activity of disease by using disease activity score DAS28.

Results: A total of 686 patients were enrolled in the study (580 female [84.5%], 106 male [15.5%]). Mean age was 53.23 \pm 12.21 and mean length of diagnosis was 10.74 \pm 7.59 months. The rate of extra-articular disease was 17.9% and the deformity rate was 31.3%. In all patients, activity of disease was mild in 55%, moderate in 37.8% and severe in 7.3% with regard to DAS28 score. The disease activity was mild in 54.6%, moderate in 43.11% and severe in 2.3% in patients who were using only NSAIDs. These rates of diseases activity was 57.2%, 40.7% and 2.1% in mild, moderate and severe disease respectively for the patients using only GK. In patients using both NSAIDs and GK, the disease activity was mild in 55%, moderate in 44% and severe in 1%. Comparison of the disease activity with medications revealed statistically significant difference in patients that using only NSAID and using both, but not in that using only steroid (respectively p: 0.022, p: 0.025, p: 0.46).

DAS 28	Mild <3,2	Moderate \geq 3,2-<5,1	Severe \geq 5,1
All patients %	55	37,8	7,3
Only NSAIDS %	54,6	43,11	2,3
Only GK %	57,2	40,7	2,1
Both NSAIDs and GK %	55	44	1,0
p	0,022	0,025	0,46

Conclusions: In our study we found that patients has mild activity of disease use highly rates of NSAID and GC. It is important for providing remission using NSAIDs and GC along with DMARD. Our results demonstrate use of both GK and NSAIDs results in better outcomes.

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AB0419 REAL WORLD USE OF TOFACITINIB IN RHEUMATOID ARTHRITIS: DATA FROM LATIN AMERICA

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Background: Tofacitinib is an oral JAK inhibitor for the treatment of RA. Tofacitinib can be given as monotherapy or with csDMARDs. Published data on real world (RW) tofacitinib use in Latin America (LA) are limited. We characterise the patient (pt) population starting tofacitinib and gain insights into the safety profile in the RW LA setting.

Methods: Initial tofacitinib therapies in adult RA pts from 10 private/public centres in 6 countries (Argentina, Brazil, Colombia, México, Panamá, Perú) were considered. Data were retrospectively obtained via a standardised format, focusing on demographics, drug history, adverse events (AEs), safety events of special interest, latent tuberculosis (TB) screening, selected confirmed laboratory abnormalities and discontinuation rates. Tofacitinib use as monotherapy or with csDMARDs was at the rheumatologist's discretion.

Results: 288 pts with severe active RA were included; most were female (n=263; 91%), mean (SD) age was 51.3 (6.36) years (yrs) and mean (SD) disease duration was 10.4 (4.0) yrs. 89% of pts were RF+ or ACPA+. The max (range) follow-up period was 22 (10–34) months. Tofacitinib was given as 2nd-line therapy (post-csDMARD) in 44% of pts, after one biologic DMARD (bDMARD) in 18% of pts and after \geq 2 bDMARDs in 38% of pts. Tofacitinib was given as monotherapy in 117/283 (41%) pts and with csDMARDs in 171/283 (59%) pts. Tofacitinib usage corresponds to 13% of advanced therapies (JAK inhibitors, bDMARDs and biosimilars). Thirty-eight AEs were observed; upper respiratory infections (n=11), skin infection (n=5), herpes zoster (HZ; n=4) and urinary infections (n=4) were most common. Gastrointestinal intolerance was seen in 2 pts. Three (1%) pts had serious infection events (SIEs); no opportunistic infections (OIs), including TB, occurred. All HZ cases (n=4; 1.4%) were monomeric, non-serious and resolved without complication after antiviral therapy. Before starting tofacitinib, 5 pts (1.7%) were vaccinated against HZ and 5.6% were diagnosed with latent TB. No active