were subjected to a hierarchical clustering analysis. The DEGs (group S vs. C and post vs. pre) were also investigated with weighted gene co-expression network analysis (WGCNA) and GO analysis. Meanwhile, the total eigengene expressions of the important modules identified by WGCNA in each cases were also calculated.

Results: Surprisingly, 8 out of the top 10 enriched GO terms in the up-regulated genes were relevant to leukocyte activation such as 'neutrophil migration' by the analysis of DEGs (post vs. pre) in group C. The cluster analysis of 'pre' genes confirmed that the patterns of gene expression between group S and C was different. WGCNA analysis of DEGs (group S vs. C) revealed that genes related to acute inflammation such as 'leukocyte mediated immunity' were activated in group S. Interestingly, it was not correlated with disease activity score (DAS) of RA. By the analysis of DEGs (post vs. pre) of upregulated genes, we found that the total eigengene expressions of the module enriched with genes related to 'cell adhesion' or 'leukocyte migration' were significantly increased in all cases of group S.

Conclusion: This is the first evidence that the genes associated with neutrophil migration is significantly activated after TCZ-Tx. It is noteworthy that the gene activation was observed in cases without any side effects. The decreased neutrophil counts in peripheral blood have been known after initiation of TCZ-Tx, which did not affect the rate of serious infections. Recently, it was reported that TCZ affects neutrophil trafficking to the bone marrow¹. Our findings will provide a rationale for its cause. On the other hand, we experienced several RA cases with development of various skin rashes associated with neutrophil activation after TCZ-Tx. However, majority of patients do not develop the side effect, even though genes related to 'neutrophil migration' are activated. In group S, our findings indicate that the genes related to 'leukocyte mediated immunity' was already activated at the initiation of treatment without correlating to DAS of RA, furthermore, the gene upregulation related to 'leukocyte migration' was more prominent after TCZ-Tx. Although it is difficult to predict the patients developing skin rashes before TCZ-Tx, we do not recommend to use TCZ for the patients with neutrophilic dermatosis which is often associated with RA.

References :

[1] Lok LSC *et al.*, *Eur J Clin Invest.* 47(10):736-745 (2017).

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SAT0120

UNITED STATES RHEUMATOLOGY PRACTICE-BASED REAL-WORLD EVIDENCE OF INFUSION REACTIONS IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH INTRAVENOUS GOLIMUMAB OR INFILIXIMAB: IMPACT OF PRIOR BIOLOGIC EXPOSURE AND METHOTREXATE UTILIZATION

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Background: AWARE (Comparative and Pragmatic Study of Golimumab IV Versus Infliximab in Rheumatoid Arthritis) is an ongoing Phase 4 comparator study designed to provide a real-world assessment of intravenous golimumab (GLM) and intravenous infliximab (IFX) in patients (pts) with rheumatoid arthritis (RA). The study recently reached its primary endpoint (comparison of overall incidence of infusion reactions in GLM- vs IFX-treated pts after 52 weeks) with the last patient reaching 52 weeks of treatment or discontinuation from the study. AWARE also records prior use of biologic medications and concomitant use of methotrexate (MTX).

Objectives: To assess the incidence of infusion reactions among GLM and IFX pts reported at baseline by examining the influence of prior biologic exposure or concurrent use of MTX.

Methods: AWARE is a prospective, noninterventional, observational, multicenter, 3-year study conducted in the US. RA patients (1,270 adults) were enrolled at the time of initiating treatment with GLM or IFX. All treatment decisions were made at the discretion of the treating rheumatologist. An infusion reaction was any adverse event that occurred during an infusion or within 1 hour after the infusion of either GLM or IFX. Imputations were not performed on these AWARE data. Data shown are mean ± standard deviation.

Results: Demographics are shown in Table 1 and the incidence of infusion reactions in different AWARE cohorts is shown in Table 2. GLM and IFX pts were comparable in sex and utilization of MTX at baseline. Both age and disease duration of GLM pts was greater than IFX pts by ~2 years. There was a higher proportion of bionative

pts in IFX-treated group compared to GLM-treated group. Overall, infusion reactions occurred more frequently among IFX-treated pts compared to GLM-treated pts. The difference in infusion reaction rates between IFX- and GLM-treated pts was also evident among subgroups of bionative vs non-bionative pts, and among MTX non-users vs MTX users (characteristics reported at baseline). GLM pts did not report any serious or severe infusion reactions. These were reported rarely (3/585 pts) in IFX-treated pts. Among GLM and IFX pts with an infusion reaction, 55.6% of GLM and 77.1% of IFX pts had at least one medication for infusion reaction. Infusion reactions accounted for 9.7% and 35.1% of discontinuations due to adverse events in GLM and IFX pts, respectively.

Table 1. Baseline Characteristics in the AWARE Study

	GLM (n=685)	IFX (n=585)
Age (years)	60.9 ± 13.43	58.0 ± 12.85
Sex (% female)	85.0 %	79.5 %
Disease Duration (years)	9.16 ± 9.975	7.20 ± 9.716
Bionative (%)	33.0%	48.6%
MTX plus (%)	75.4%	75.1%

MTX=methotrexate

Table 2. Infusion Reactions in AWARE in Subsets of Patients ± Prior Biologic Use or ± Concurrent MTX

	GLM (n=685)		IFX (n=585)		GLM (n=685)		IFX (n=585)	
	Bionative	Non-Bionative	Bionative	Non-Bionative	No MTX Use	MTX Use	No MTX Use	MTX Use
Infusion Reactions	6/242 (2.5%)	21/443 (4.7%)	36/251 (14.3%)	47/334 (14.1%)	15/265 (5.7%)	12/420 (2.9%)	44/229 (19.2%)	39/356 (11.0%)
Medication for Infusion Reactions	33.3%	59.1%	78.9%	73.6%	50.0%	58.3%	73.6%	77.6%

MTX=methotrexate

Conclusion: Whether bionative, non-bionative, MTX non-user or MTX user at baseline, the incidence of infusion reactions was notably lower among GLM- vs IFX-treated pts. Serious and/or severe infusion reactions did not occur among GLM pts and were rare among IFX pts. IFX was more commonly administered medication for an infusion reaction compared to GLM. Infusion reactions accounted for almost four times the number of discontinuations related to adverse events in IFX pts compared to GLM pts.

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SAT0121

PAIN AND OTHER PATIENT-REPORTED OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO DID OR DID NOT ACHIEVE TREATMENT RESPONSE BASED ON IMPROVEMENT IN SWOLLEN JOINTS IN TOCILIZUMAB CLINICAL TRIALS

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Background: Significant improvements in pain and other patient-reported outcomes (PROs) have been shown in large clinical trials in patients with rheumatoid arthritis (RA) who receive tocilizumab (TCZ) compared with placebo (PBO). Recent data suggest that pain in RA may be noninflammatory as well as inflammatory, and