

FRI0280 IMPACT OF DISEASE DURATION BEFORE STARTING ADALIMUMAB TREATMENT ON WORK PRODUCTIVITY IN JAPANESE PATIENTS WITH RHEUMATOID ARTHRITIS; ANALYSIS OF 24-WEEKS DATA FROM THE ANOUVEAU STUDY

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Background: Treatment with adalimumab (ADA) has been reported to improve work productivity and reduce indirect cost due to work impairment in patients with rheumatoid arthritis (RA). The impact of disease duration at the time of treatment initiation on work impairment is less well understood.

Objectives: To assess the impact of disease duration before starting treatment with ADA on work productivity and economic benefit in Japanese patients with RA.

Methods: Data were taken from the first 24 weeks of a 48-week, multicenter, prospective, single-cohort study of self-reported work productivity and activity impairment in 897 Japanese patients with RA receiving ADA.¹ Patients were divided by quartiles (Q) based on disease duration at the time of ADA initiation. Work-related outcomes (absenteeism, presenteeism, overall work impairment [OWI], and activity impairment [AI]) were measured using the Work Productivity and Activity Impairment questionnaire for rheumatoid arthritis (WPAI/RA). Disease activity score based on 28 joint counts (DAS28) and the Health Assessment Questionnaire Disability Index (HAQ-DI) were used to assess clinical and functional response, respectively. For the comparison of changes in clinical response and WPAI domain scores by quartiles of disease duration, contrast test (linear trend) was performed with adjustments for baseline factors. Life saved productivity loss was estimated using OWI score and basic wages in Japanese workers 2012 by Ministry of Health Labor and Welfare.

Results: At week 24, disease activity measures and WPAI/RA domain scores were significantly improved across quartiles. There were statistically significant decreasing trends in the percentage of patients achieving DAS28-ESR and HAQ-DI remission after 24 weeks of treatment with longer disease duration. Similarly, there were statistically significant decreasing trends in changes of OWI and AI (activity impairment) from baseline to week 24 with increasing disease duration (table). The estimated life saved productivity losses due to OWI for paid workers in this analysis were €88,292 for Q1, €61,541 for Q2, €55,677 for Q3 and €36,177 for Q4 (€1 = \$1.40).

Quartiles	Q1	Q2	Q3	Q4	p*	
Disease duration (years)	≤1.3	1.3<≤4	4<≤11	11<		
n	224	232	227	214		
Remission rate** (%)	DAS28-ESR	43.2	40.2	32.9	20.9	0.0144
	HAQ-DI	49.6	51.8	41.2	19.5	<0.0001
Changes from baseline to week 24*** (%)	OWI	18.9	16.7	12.0	9.2	0.0240
	AI	23.8	17.8	15.7	12.7	0.0237

*: contrast test (linear trend) was performed by adjusted for following baseline factors: disease duration, DAS28-ESR, HAQ-DI, Absenteeism, Prior biologics for DAS28-ESR; disease duration, HAQ-DI, EQ5D, PSL for HAQ-DI; disease duration, HAQ-DI, OWI, Absenteeism, MTX for OWI; disease duration, DAS28-ESR, HAQ-DI, Presenteeism, AI, MTX, Prior biologics for AI. **: percentage of patients achieving remission (DAS28-ESR <2.6, HAQ-DI ≤0.5) after 24 week of treatment. ***: data are indicated as mean.

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Conclusions: Shorter disease duration before starting ADA treatment leads to better clinical response and work related outcomes in Japanese patients with RA. Earlier ADA treatment has an economic impact on lifetime benefit in Japanese RA patients.

References:

[1] Y. Tanaka, et al. ACR2013, Poster #2366

Acknowledgements: This study was sponsored by AbbVie and Eisai Co., Ltd. AbbVie contributed to the study design, research, and interpretation of data, writing, reviewing, and approving the publication.

Disclosure of Interest: T. Takeuchi Grant/research support: AbbVie GK., Astellas Pharma, Bristol-Myers K.K., Chugai Pharmaceutical Co. Ltd., Daiichi Sankyo Co., Ltd., Eisai Co., Ltd., Janssen Pharmaceutical K.K., Mitsubishi Tanabe Pharma Co., Nippon Shinyaku Co., Ltd., Pfizer Japan Inc., Sanofi-Aventis K.K., Santen Pharmaceutical Co., Ltd., Takeda Pharmaceutical Co., Ltd., and Teijin Pharma Ltd., Consultant for: Astra Zeneca K.K., Eli Lilly Japan K.K., Novartis Pharma K.K., Mitsubishi Tanabe Pharma Co., and Asahi Kasei Medical K.K. Speakers bureau: AbbVie GK., Bristol-Myers K.K., Chugai Pharmaceutical Co., Ltd., Eisai Co., Ltd., Janssen Pharmaceutical K.K., Mitsubishi Tanabe Pharma Co., Pfizer Japan Inc., and Takeda Pharmaceutical Co., Ltd., Y. Shinmura Employee of: AbbVie GK, R. Nakajima Employee of: AbbVie GK, K. Hiramatsu Employee of: AbbVie GK, T. Kubo Employee of: AbbVie GK, A. Kimoto Employee of: AbbVie GK, A. Kuroki Employee of: AbbVie GK, A. Igarashi Grant/research support: TOWA Pharmaceutical Co., Ltd., Consultant for: AbbVie GK., Abbott Japan Co., Ltd., Boehringer Ingelheim Japan, Inc., Novartis Pharma K.K., and Pfizer Japan Inc., T. Tango Consultant for: AbbVie GK., Ajinomoto Pharma, Hospira Japan Co.,

Ltd., Y. Tanaka Grant/research support: Bristol-Myers, Mitsubishi-Tanabe, AbbVie, MSD, Chugai, Astellas, Daiichi-Sankyo, Consultant for: Mitsubishi-Tanabe, Eisai, Chugai, Abbott Japan, Astellas, Daiichi-Sankyo, AbbVie, Janssen, Pfizer, Takeda, Astra-Zeneca, Eli Lilly Japan, GlaxoSmithKline, Quintiles, MSD, Asahi-Kasei, Speakers bureau: Mitsubishi-Tanabe, Eisai, Chugai, Abbott Japan, Astellas, Daiichi-Sankyo, AbbVie, Janssen, Pfizer, Takeda, Astra-Zeneca, Eli Lilly Japan, GlaxoSmithKline, Quintiles, MSD, Asahi-Kasei
DOI: 10.1136/annrheumdis-2014-eular.2192

FRI0281 THE RATE OF POSITIVE CONVERSION IN THE QUANTIFERON-TB GOLD TEST OVER 2 YEARS AMONG PATIENTS TREATED WITH CT-P13 OR INNOVATOR INFlixIMAB IN THE EXTENSION STUDIES OF PLANETAS AND PLANETRA

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Background: Long-term treatment of anti-TNF agents in patients with immune mediated disease can increase the risk of active tuberculosis infection (ATBI) by reactivation of latent tuberculosis infection (LTBI) or de novo infection. CT-P13 is a biosimilar of innovator infliximab (INX), approved by the EMA in 2013 based on the studies PLANETAS and PLANETRA.

Objectives: To identify the risk of positive conversion in the QuantiFERON®-TB Gold in-tube (QTF) test over 2 years in ankylosing spondylitis (AS) and rheumatoid arthritis (RA) patients receiving CT-P13 or INX in the extension studies of PLANETAS and PLANETRA, in 17 countries with various TB incidences.

Methods: Of 476 enrolled subjects in extension studies of PLANETAS or PLANETRA, all patients had QTF test at baseline and at least one follow-up QTF result after study drug exposure for a 110-week period. Patients with positive QTF result at baseline received prophylaxis before study drug exposure. Patients received either CT-P13 or INX (5mg/kg in AS; 3mg/kg in RA) by usual schedule up to week 102. Countries were divided into four risk groups according to TB incidence, as listed in the 2013 WHO TB report: very low (0–19/100000 population), low (20–49), intermediate (50–124) and high (≥125). In prevalent countries, QTF was performed at weeks 14, 30, 54, 62 and 110. In countries with low risk, QTF was performed at weeks 62 and 110 (or the end of the study visit). To identify the positive conversion in QTF test, patients with negative result at baseline were included in this analysis.

Results: Among 458 patients with negative QTF at baseline, median dose is 15 (range 9 to 15) and all patients had at least one QTF result after 9th dose exposure. Positive conversion of QTF was observed in 16.6% (76/458) of patients (AS 18.5% [31/168]; RA 15.5% [45/290]). The results showed a tendency of higher positive conversion rate in the region where the TB incidence is high (very low 9.3%, low 11.4%, intermediate 21.7%, high 52.0%). Relative risk (RR) of positive conversion in intermediate and high vs. very low and low TB incidence countries was 2.37 (95% CI 1.57 to 3.59). Non-white ethnicity had higher RR of positive conversion in very low and low TB incidence countries (RR 3.83, 95% CI 2.04 to 7.21), and intermediate and high TB incidence countries (RR 3.11, 95% CI 1.89 to 5.10) as well. In very low, low, intermediate and high incidence countries, positive conversion was observed in 9.3%, 8.5%, 19.6% and 48.0% of patients at week 62, and 0%, 3.0%, 2.1% and 4.0% of patients after week 62 over 2 years, respectively. Amongst patients who had positive conversion, 76.3% (58/76) of patients received prophylactic TB medication.

Conclusions: To reduce TB incidence in patients receiving anti-TNF agents, appropriate screening and serial QTF tests at least during the first two years of treatment are necessary to reduce and minimize the risk of TB in patients residing in intermediate and high TB endemic regions.

Disclosure of Interest: W. Park Grant/research support: CELLTRION, Inc., Consultant for: CELLTRION, Inc., Speakers bureau: CELLTRION, Inc., D. Yoo Grant/research support: CELLTRION, Inc., Consultant for: CELLTRION, Inc., Speakers bureau: CELLTRION, Inc., P. Hrycaj Grant/research support: CELLTRION, Inc., N. Prodanovic Grant/research support: CELLTRION, Inc., P. Miranda Grant/research support: CELLTRION, Inc., E. Ramitter Grant/research support: CELLTRION, Inc., A. Baranuskaitė Grant/research support: CELLTRION, Inc., P. Wiland Grant/research support: CELLTRION, Inc., Y.-A. Lee Grant/research support: CELLTRION, Inc., S. Lee Employee of: CELLTRION, Inc.

DOI: 10.1136/annrheumdis-2014-eular.3492