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SAFETY AND EFFECTIVENESS OF CT-P13 IN PATIENTS WITH RHEUMATOID ARTHRITIS: RESULTS FROM 24 MONTHS NATIONWIDE REGISTRY IN KOREA

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My abstract has been or will be presented at a scientific meeting during a 12 months period prior to EULAR 2017: No

Is the first author applying for a travel bursary and/or an award for undergraduate medical students?: No

Background: CT-P13 is approved in both European Union and United States, and licensed for use in 79 countries around the world as a biosimilar to innovator infliximab (INX). The independent registries of CT-P13 have been conducted in a number of European countries and Korea [1].

Objectives: To evaluate safety and effectiveness of CT-P13 when administered in a real-life setting in active RA patients.

Methods: This study collected data of patients who were treated with CT-P13 from 2013 December to 2016 June. Efficacy was assessed at baseline and every 6 months thereafter using DAS28 (ESR) and/or DAS28 (CRP) and collection of adverse events (AEs) was performed. Immunogenicity was assessed at baseline, Week 30 and every year during CT-P13 treatment period.

Results: Total 125 patients were enrolled; 104 patients started treatment with CT-P13 (Naïve group) and 21 patients (8 from INX, 13 from other anti-TNFs) switched treatment to CT-P13 (Switching group). The mean (SD) duration since RA diagnosis was 6.5 (±6.85) years for all patients.

Of all patients treated with CT-P13, only 4.8% (6/125) of patients changed to other anti-TNFs. Two of six patients changed treatment within 8 month after starting CT-P13.

The proportion of patients achieving clinical remission by DAS28 (ESR/CRP) increased gradually (Figure 1). DAS28 (ESR/CRP) value decreased from baseline at 6 months and it maintained thereafter (Table 1). Switching group also showed similar results that remission rate by DAS28 (CRP) was 42.9% (3/7) and mean actual value was 2.85 at 12 Months.

For Naïve group, 50% (52/104) of patients had at least one positive anti-drug antibody result and it is consistent to other published study [2].

Overall safety summarized as the percentage of patients with at least one treatment emergent AE (TEAE) was similar or lower after switching to CT-P13 (Table 2). No cases of active tuberculosis were reported.

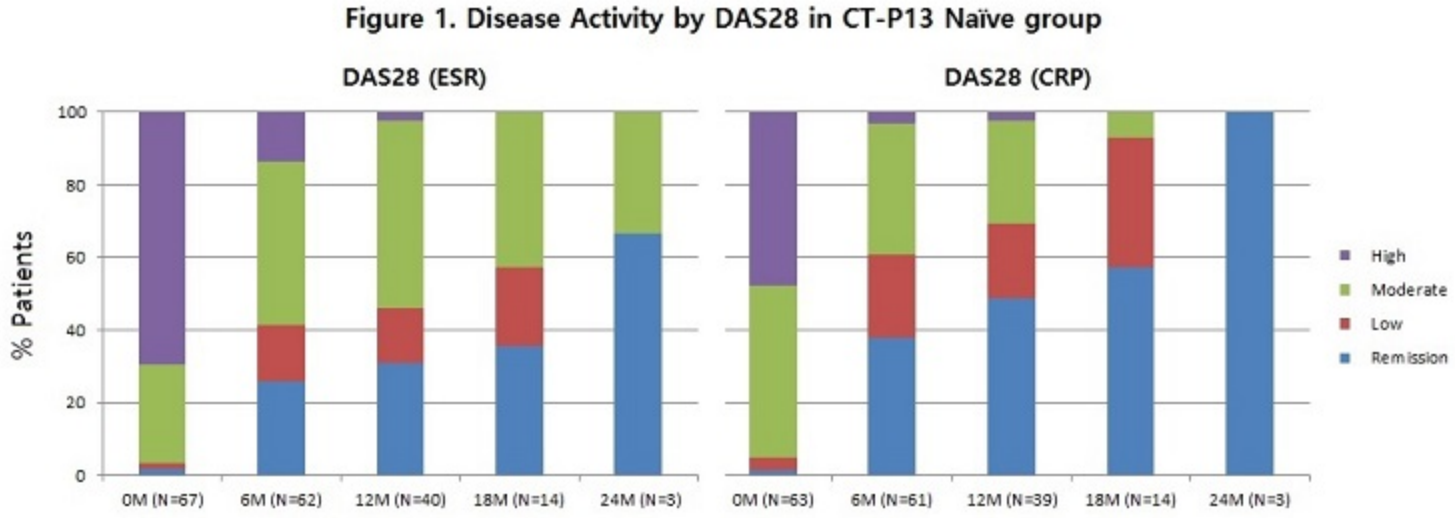
Table 1. DAS28 in CT-P13 Naïve group over 24 months

		Baseline	6 months	12 months	18 months	24 months
DAS28 (ESR)	n	67	62	40	14	3
	Mean	5.78	3.61	3.30	3.01	2.42
	SD	1.14	1.40	1.22	1.03	0.74
DAS28 (CRP)	n	63	61	39	14	3
	Mean	5.06	2.97	2.59	2.35	1.81
	SD	1.19	1.21	1.06	0.69	0.63

Table 2. Safety results in CT-P13 Naïve and Switching group

	Naïve group	**Switching group**
TEAEs	80.8% (84/104)	66.7% (14/21)
Related TEAEs	31.7% (33/104)	28.6% (6/21)
Infection and Infestation	42.3% (44/104)	33.3% (7/21)

Image/graph:



Conclusions: The overall safety profile revealed that CT-P13 is well-tolerated in patients with RA and remission rate for 24 months also showed that CT-P13 is efficacious under real world practice.

References: 1. Glintborg et al. ACR 2016
2. Krintel et al. Rheumatology 2013

Disclosure of Interest: None declared