POS0911

SIMILAR CLINICAL RESPONSES ACHIEVED WITH LOWER VERSUS STANDARD DOSES OF INFLIXIMAB BIOSIMILAR CT-P13 IN PATIENTS WITH ANKYLOSING SPONDYLITIS: REAL-WORLD RESULTS FROM THE RAAS STUDY

S. S. Lee¹, T. H. Kim², W. Park³, Y. W. Song⁴, C. H. Suh⁵, S. Kim⁶, D. Yoo².
¹Chonnam National University Medical School & Hospital, Department of Rheumatology, Gwangju, Korea, Rep. of (South Korea); ²Hanyang University Hospital for Rheumatic Diseases, Department of Rheumatology, Seoul, Korea, Rep. of (South Korea); ³Inha University, School of Medicine, Incheon, Korea, Rep. of (South Korea); ⁴Seoul National University College of Medicine, Seoul National University Hospital, Department of Internal Medicine, Division of Rheumatology, Seoul, Korea, Rep. of (South Korea); ⁵Ajou University School of Medicine, Department of Rheumatology, Suwon, Korea, Rep. of (South Korea); ⁶Celltrion Healthcare Co., Ltd., Medical Affairs Department, Incheon, Korea, Rep. of (South Korea)

Background: CT-P13, an infliximab biosimilar, is effective for treating ankylosing spondylitis (AS) at a dose of 5 mg/kg infused once every 6–8 weeks. Evidence suggests that patients with AS may benefit from a lower dose, and individualised dose/interval adjustments should be based on treatment response.

Objectives: To analyse real-world treatment patterns (doses and infusion intervals) and outcomes for CT-P13-treated patients with AS over 5 years.

Methods: The RAAS study collected medical record data for adults with AS treated with CT-P13 at five referral hospitals in the Republic of Korea (2012–2017). Patients were infliximab naïve at CT-P13 initiation ('naïve') or had switched to CT-P13 from reference infliximab ('switched'). Patients were analysed by baseline dose (BD) (<4 mg/kg; ≥4–<5 mg/kg; ≥5 mg/kg), defined as the third (naïve) or first (switched) infusion dose. Baseline infusion intervals were the average of the three infusion intervals after BD. Over time, patients with both constant dose and infusion interval were compared with those with changes in dose and/or infusion interval. Data were analysed by Kruskal–Wallis test, chi-squared test and one-way analysis of variance, and drug survival by log-rank test.

Results: Overall, 337 patients (219 naïve; 118 switched) were identified. Of those with BD data, 71, 117 and 82 patients had BDs of <4 mg/kg, ≥4–<5 mg/kg and ≥5 mg/kg, respectively. Most patients were male (74.8%). Patients with higher BDs tended to have higher Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores; switched patients had lower scores than naïve patients. Of 186 evaluable patients (118 naïve; 68 switched), 85 (46 naïve; 39 switched) did not have dose and/or interval changes ('combined constant' group). More naïve (n=72; 61.0%) versus switched (n=29; 42.6%) patients had dose and/or interval changes ('combined changed' group). Considering dose and interval separately, 18/235 evaluable patients (152 naïve; 83 switched) had dose changes (12 increased; 6 decreased) and 110/224 evaluable patients (140 naïve; 84 switched) had interval changes (79 increased; 31 decreased). Cumulative annual doses were similar between naïve and switched patients; switched patients had longer infusion intervals than naïve patients (Figure 1). There were no significant differences in drug survival between BD groups overall or for naïve and switched patients. BASDAI scores over time showed that disease activity was well controlled (Table 1). Patients in the combined changed versus combined constant group had greater improvements in BASDAI score.

Table 1. BASDAI scores

Group		Statistic	W0	W54	W102	W156	W210	
Combined constant	Total (N=85)	n	72	73	57	42	31	
		Mean	5.50	2.50	2.35	2.42	2.36	
		(SD)	(3.12)	(1.71)	(1.66)	(1.66)	(1.68)	
	Median	6.32	2.60	2.40	2.55	2.60		
		Naïve (n=46)	n	39	39	26	18	12
			Mean	7.86	2.49	2.41	2.34	1.94
	(SD)		(1.45)	(1.82)	(1.75)	(1.70)	(1.58)	
	Switched (n=39)	Median	7.80	2.20	1.75	1.90	1.44	
		n	33	34	31	24	19	
		Mean	2.71	2.50	2.31	2.48	2.63	
	(SD)	(2.07)	(1.60)	(1.60)	(1.67)	(1.73)		
	Combined changed	Total (N=101)	Median	2.58	2.75	2.50	2.80	2.70
n			87	85	76	53	35	
Mean			5.68	1.81	1.58	1.49	1.40	
Naïve (n=72)		(SD)	(2.89)	(1.45)	(1.27)	(1.34)	(1.24)	
		Median	6.70	1.32	1.19	1.20	1.00	
		n	63	60	54	34	18	
Switched (n=29)		Mean	7.18	2.01	1.65	1.54	1.52	
		(SD)	(1.37)	(1.44)	(1.22)	(1.26)	(0.97)	
		Median	7.30	1.83	1.35	1.31	1.35	
Switched (n=29)		n	24	25	22	19	17	
		Mean	1.74	1.33	1.42	1.39 (1.50)	1.28	
		(SD)	(1.94)	(1.36)	(1.41)		(1.50)	
Median	0.92	0.80	0.85	0.70	0.58			

SD, standard deviation; W, Week

Figure. Mean cumulative annual dose and mean infusion interval by treatment group

Conclusion: These real-world data demonstrate that adjusting dose and infusion interval can improve clinical outcomes for CT-P13-treated patients with AS. Drug survival and BASDAI results show that patients with lower baseline BASDAI receiving low CT-P13 doses can achieve the same outcomes as those dosed with ≥5 mg/kg. Findings support the lack of impact of switching from reference infliximab to CT-P13 on efficacy, underlining conclusions previously drawn for efficacy and safety.¹

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POS0912

LONG-TERM TREATMENT WITH IXEKIZUMAB IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: TWO-YEAR RESULTS FROM COAST-Y

J. Braun^{1,2}, U. Kiltz^{1,2}, A. Deodhar³, T. Tomita⁴, M. Dougados⁵, R. Bolce⁶, D. Sandoval⁶, D. Adams⁶, C. Y. Lin⁶, J. A. Walsh⁷. ¹Rheumazentrum Ruhrgebiet, Rheumatology, Herne, Germany; ²Ruhr-Universität Bochum, Rheumatology, Herne, Germany; ³Oregon Health & Science University, Rheumatology, Portland, United States of America; ⁴Osaka University Graduate School of Medicine, Rheumatology, Osaka, Japan; ⁵Hôpital Cochin, Rheumatology, Paris, France; ⁶Eli Lilly and Company, Biomedicines, Indianapolis, United States of America; ⁷University of Utah, Rheumatology, Salt Lake City, United States of America

Background: The efficacy and safety of the interleukin-17 inhibitor ixekizumab (IXE) for the treatment of radiographic (r-) and non-radiographic (nr-) axial spondyloarthritis (axSpA) has been shown for up to 52 weeks.^{1,2}

Objectives: To study the efficacy and safety of ixekizumab in the treatment of patients with r- and nr-axSpA for up to 116 weeks.

Methods: COAST-Y (NCT03129100) is the 2-year extension of the COAST-V, -W, and -X trials. Patients continued with the dose received at the end of the originating trial at Week 52, either with 80 mg IXE every 4 weeks (Q4W) or every 2 weeks (Q2W). Patients who had been assigned to adalimumab or placebo were re-randomized to IXE Q4W or Q2W at Week 16 in COAST-V and -W. Patients who had received placebo for 52 weeks in COAST-X were switched to IXE Q4W in COAST-Y. Patients who switched from placebo or adalimumab treatment to IXE (COAST-V, -W, or -X) or from IXE Q4W to open-label IXE Q2W (COAST-X) during the originating studies were analyzed separately from patients continuously treated with IXE. Standardized efficacy measures were used (Table 1). Missing data were handled by non-responder imputation for categorical data

and modified baseline observation carried forward for continuous data. Safety data were analyzed for all patients who received ≥ 1 dose of IXE.

Table 1. Demographic and efficacy results for patients continuously treated with IXE for 116 weeks

	IXE Q4W N=157		IXE Q2W N=195	
Demographics				
Age	42.7 (13.0)		41.8 (11.2)	
Male (n, [%])	124 (79.0)		132 (67.7)	
Baseline ASDAS	3.92 (0.80)		3.95 (0.76)	
Baseline BASDAI	7.07 (1.26)		7.18 (1.35)	
Baseline BASFI	6.57 (1.76)		6.74 (1.86)	
Baseline BASMI	4.08 (1.46)		3.97 (1.52)	
Baseline SF-36 PCS	33.90 (7.27)		33.26 (6.88)	
Outcome measure				
Response (n, [%])	Week 52	Week 116	Week 52	Week 116
ASDAS <2.1	75 (47.8)	69 (43.9)	88 (45.1)	96 (49.2)
ASAS partial remission	34 (21.7)	31 (19.7)	35 (17.9)	39 (20.0)
ASAS40	82 (52.2)	89 (56.7)	99 (50.8)	108 (55.4)
BASDAI50	78 (49.7)	75 (47.8)	83 (42.6)	99 (50.8)
Change from baseline				
ASDAS	-1.64 (1.05)	-1.60 (1.15)	-1.63 (1.03)	-1.78 (1.04)
BASFI	-2.88 (2.31)	-2.76 (2.39)	-2.83 (2.38)	-3.15 (2.34)
BASMI	-0.57 (0.95)	-0.57 (0.93)	-0.53 (0.92)	-0.60 (1.00)
SF-36 PCS	9.03 (8.62)	8.43 (8.70)	8.87 (7.57)	9.86 (8.45)

Data are mean (SD) unless otherwise noted. Non-responder imputation was used for categorical variables, and modified baseline observation carried forward for continuous variables.

Results: Of the 773 patients enrolled in COAST-Y, 86.0% completed Week 116 of treatment (52 weeks of one of the originating trials and 64 weeks of COAST-Y). Among the patients continuously treated with IXE for 116 weeks (IXE Q4W: N=157; IXE Q2W: N=195), 46.9% achieved low disease activity (ASDAS <2.1), and 19.9% achieved ASAS partial remission at 116 weeks (Table 1; Figure 1). In comparison to baseline, 56.0% achieved ASAS40 (Table 1). The mean change from baseline at Week 116 was -1.70 for ASDAS, -2.98 for BASFI, and 9.22 for SF-36 Physical Component Summary (Table 1). Similar observed responses were achieved between the patients continuously treated with IXE and patients initially treated with placebo or adalimumab. For the 932 patients in the safety population, no new safety signals were identified.

Conclusion: Ixekizumab treatment led to consistent and sustained long-term improvements in disease activity and quality of life in patients with r- and nr-ax-SpA, with no new safety signals after up to 2 years of treatment.

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Figure: ASDAS <2.1 responses for patients continuously treated with IXE for 116 weeks

Non-responder imputation was used for ASDAS <2.1.

Abbreviations (Table and Figure): ASAS40=achieving 40% improvement in Assessment of SpondyloArthritis International Society (ASAS) criteria; ASDAS=Ankylosing Spondylitis Disease Activity Score; BASDAI50=achieving 50% improvement in Bath Ankylosing Spondylitis Disease Activity Index; BASFI=Bath Ankylosing Spondylitis Functional Index; BASMI=Bath Ankylosing Spondylitis Metrology Index; IXE=ixekizumab; Q2W=every 2 weeks; Q4W=every 4 weeks; SF-36 PCS=36-item Short-Form Health Survey Physical Component Summary.

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POS0913 UVEAL CATARACT IN PATIENTS WITH SPONDYLOARTHRITIS AND OTHER IMMUNO-INFLAMMATORY DISEASES AND ITS SURGICAL TREATMENT

S. Avetisov^{1,2}, I. Razumova³, K. Avetisov⁴, A. Godzenko⁵. ¹Federal State Budgetary Scientific Institution Research Institute of Eye Diseases, Chief Scientific Adviser, Moscow, Russian Federation; ²I.M. Sechenov First Moscow State Medical University (Sechenov University), Department of Eye Diseases, Moscow, Russian Federation; ³Federal State Budgetary Scientific Institution Research Institute of Eye Diseases, Retinal and Optic Nerve Pathologies, Moscow, Russian Federation; ⁴Federal State Budgetary Scientific Institution Research Institute of Eye Diseases, Department of Modern Methods of Treatment, Moscow, Russian Federation; ⁵Federal State Budgetary Educational Institution of Additional Professional Education Russian Medical Academy of Continuous Professional Education, Rheumatology, Moscow, Russian Federation

Background: Uveitis is a common extra-skeletal manifestation of various systemic diseases, in particular, spondyloarthritis (SpA). Uveal cataract is the frequent complication of endogenous uveitis. Surgical treatment of uveal cataracts is associated with certain problems, the main being a potential risk of recurrence of uveitis, especially in the case of intraocular lens (IOL) implantation.

Objectives: To analyse the results of surgery of complicated uveal cataract in patients with SpA and other rheumatic disorders.

Methods: 30 pts (34 eyes) with uveal cataract as a result of systemic immuno-inflammatory diseases were assessed in the "Research Institute of Eye Diseases" in the period from 2006 to 2018. The postoperative follow-up period ranged from 2 to 12 years. 20 pts had different variants of SpA (Group 1): 7 (7 eyes) - ankylosing spondylitis, 1 (1 eye) - reactive arthritis, 1 (1 eye) - psoriatic arthritis, 4 (6 eyes) - juvenile spondyloarthritis, 8 (8 eyes) non-radiological SpA. 10 patients (11 eyes) had other systemic diseases (Group 2): 1 (1 eye) Behcet's disease, 1 (1 eye) - multiple sclerosis, 3 (3 eyes) - Fuchs heterochromic cyclitis, 2 (2 eyes) - cutaneous psoriasis, and 3 (4 eyes) - uveitis of unknown etiology. 4 pts (6 eyes) with juvenile arthritis and pronounced corneal ribbon degeneration were underwent standard intracapsular cryoextraction of the cataract, followed by optical correction of aphakia using spectacle lenses. In other cases, ultrasound phacoemulsification with IOL implantation was used as a surgical aid. All patients had a period of uveitis remission before operation for at least 2 months. Anti-inflammatory therapy using local glucocorticoid and local and systemic nonsteroidal antiinflammatory drugs was prescribed 2 weeks before and within a month after the operation. Intra and postoperative complications, fluctuations in intraocular pressure (IOP), improvement of visual acuity, and the frequency of uveitis flares after surgery were assessed as the main criteria for analyzing the results of surgery.

Results: A statistically significant decrease in the number of uveitis exacerbations was observed in all pts: in group 1 - from 2.5 ± 0.65 to 1.2 ± 0.65 per year ($p < 0.0001$), in group 2 - from 2.55 ± 0.21 to 0.89 ± 0.21 per year ($p < 0.0001$), while there were no statistically significant differences between the groups ($p = 0.31$). Statistically significant increase in maximum visual acuity was observed in all groups: in group 1 - from 0.2 ± 0.38 to 0.58 ± 0.74 , $p < 0.0001$, in group 2 - from 0.24 ± 0.05 to 0.69 ± 0.07 , $p < 0.0001$. No complications were observed during operations. The phenomena of bullous keratopathy after intracapsular extraction were noted in 2 pts with juvenile arthritis and ribbon-like corneal degeneration. No progression of corneal changes was observed. Opacity in the central zone of the posterior capsule in the period from 2 to 24 months after surgery occurred in 7 cases. In all cases, laser dissection of the posterior lens capsule was performed. Transient increase in IOP in the early postoperative period, normalized by local hypotensive therapy, occurred in 8 cases in groups I. In the long-term follow-up period (2-24 months), persistent IOP decompensation occurred in 6