Chugai, Eli Lilly, Grünenthal, Janssen, MSD, Novartis, Pfizer, Roche, and UCB., Consultant for: AbbVie, Chugai, Eli Lilly, Grünenthal, Janssen, MSD, Novartis, Pfizer, Roche, and UCB., Theresa Hunter Employee of: Eli Lilly and Company, Yan Dong Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Ann Leung Employee of: Syneos Health, David Sandoval Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Luis Leon Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Vibeke Strand Consultant for: AbbVie, Amgen, Bayer, BMS, Boehringer Ingelheim, Celgene, Celltrion, CORRONA, Crescendo, EMD Serono, Genentech/Roche, GSK, Horizon, Inmedix, Janssen, Kezar, Lilly, Merck, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi, Servier, UCB.

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AB0711

IXEKIZUMAB IMPROVES SIGNS AND SYMPTOMS AND SPINAL INFLAMMATION OF ANKYLOSING SPONDYLITIS/RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS THROUGH ONE YEAR OF TREATMENT IN BIOLOGIC DISEASE MODIFYING ANTI-RHEUMATIC DRUG-NAÏVE PATIENTS

James Cheng-Chung Wei¹, Lianne S. Gensler², Jessica A. Walsh³, Robert B. M. Landewé⁴, Tetsuya Tomita⁵, Fangyi Zhao⁶, Gaia Gallo⁶, Hilde Carlier⁵, Maxime Dougados⁷. ¹Chung Shan Medical University Hospital, Taichung City, Taiwan, Republic of China; ²UCSF School of Medicine, San Francisco, United States of America; ³University of Utah, Salt Lake City, United States of America; ⁴University of Amsterdam and Atrium Medical Center, Heerlen, Netherlands; ⁵Osaka University Graduate School of Medicine, Osaka, Japan; ⁶Eli Lilly and Company, Indianapolis, United States of America; ⁷Rene Descartes Univ/Cochin Hospital, Paris, France

Background: During 16 weeks (wks) of blinded treatment, ixekizumab (IXE) and an adalimumab (ADA) active reference arm were superior to placebo (PBO) in improving signs and symptoms of radiographic axial spondyloarthritis (r-axSpA).¹

Objectives: To assess the safety and efficacy of continuous treatment with IXE through 52 wks in patients (pts) with r-axSpA and to describe clinical response at Wk 52 for pts who switched to IXE following 16 wks of treatment with either ADA or PBO.

Methods: Participants were biologic disease-modifying anti-rheumatic drug (bDMARD)-naïve adult pts with active r-axSpA per Assessment of Spondyloarthritis (SpA) international Society (ASAS) criteria (sacroiliitis centrally defined by modified New York criteria and ≥ 1 SpA feature) and inadequate response or intolerance to non-steroidal anti-inflammatory drugs. Pts were randomized 1:1:1:1 to receive 80 mg IXE every 2 (Q2W) or 4 wks (Q4W), 40 mg adalimumab (ADA) Q2W (active reference arm), or PBO. At Wk 16, pts assigned to IXE continued their assigned treatment and pts receiving PBO or ADA were re-randomized 1:1 to IXE Q2W or IXE Q4W through Wk 52.

Results: Of 164 pts initially randomized to IXE, 146 (89%) completed Wk 52. IXE Q4W and IXE Q2W led to persistent improvements in disease activity, function, objective inflammation (MRI and C-reactive protein), quality of life, health status, and overall functioning for up to 52 wks (Figure and Table). For pts initially assigned to PBO or ADA, ASAS40 response showed a numerical increase upon switching to IXE (Table). Frequencies of treatment-emergent adverse events (AEs) were similar between IXE dosing regimens. Among pts with ≥ 1 dose of IXE (N=336), serious AEs occurred in 20 (6%) pts. There were no deaths and 11 (3%) pts discontinued due to AEs.

Analyses were conducted on the intent-to-treat population according to initially assigned treatments. Adalimumab represents an active reference arm. The study was not powered to test equivalence or non-inferiority of the active treatment arms to each other, including ixekizumab versus adalimumab. ASAS = Assessment of Spondyloarthritis International Society, ASAS = Ankylosing Spondylitis Disease Activity Scale, BASDAI 50 = $\geq 50\%$ improvement from baseline in the Bath Ankylosing Spondylitis Disease Activity Index, CII = Clinically Important Improvement (ASAS change from baseline ≥ 1), MI = Major improvement (ASAS change from baseline ≥ 2 or reached the minimum ASAS score), Q2W = every 2 weeks, Q4W = every 4 weeks.

Efficacy of IXE in bDMARD-naïve patients with active r-axSpA

Mean (± SD) change from baseline, Week 52 mBOCF (intent-to-treat)	IXE Q4W (N=81)	IXE Q2W (N=83)	
ASDAS-CRP	-1.7 (1.2)	-1.6 (1.0)	
BASDAI ^a	-3.3 (2.5)	-3.1 (2.3)	
C-Reactive Protein (mg/L)	-9.2 (12.4)	-9.6 (14.5)	
BASFI	-2.8 (2.5)	-2.8 (2.4)	
SF-36 PCS ^b	8.3 (9.5)	8.1 (7.5)	
ASAS Health Index	-2.7 (3.3)	-3.3 (3.6)	
SPARCC Spine Score (observed) ^c	-8.8 (17.3)	-8.5 (15.9)	
Response (%)	PBO/All	ADA/All	All IXE/All
NRI, extended treatment period population ^d	IXE (N=86)	IXE (N=86)	IXE (N=164)
ASAS40			
Week 16	18.6	36.0	50.0
Week 52	46.5	51.2	51.8

^aBASDAI items were scored on a 0-10 numeric rating scale

^bSF-36 analyses based on 2009 US norms

^cSPARCC Spine: N=72 (IXE Q4W), N=68 (IXE Q2W)

^dPatients who received ≥ 1 dose of IXE during Weeks 16-52

ADA=adalimumab; BASFI=Bath Ankylosing Spondylitis Functional Index; IXE=ixekizumab; mBOCF=modified Baseline Observation Carried Forward; NRI=nonresponder imputation; PBO=Placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; SF-36 PCS=Medical Outcomes Study 36-Item Short-Form Health Survey Physical Component Summary; SPARCC=Spondyloarthritis Research Consortium of Canada

Conclusion: Persistent improvements in the signs and symptoms of r-axSpA were observed through Wk 52 in pts who received continuous treatment with IXE. ASAS40 response rates at Wk 52 were numerically similar between pts who received continuous treatment with IXE and pts who switched from ADA to IXE. No unexpected safety signals were observed through 52 wks of treatment.

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Spondyloarthritis – clinical aspects (other than treatment)

AB0712

RETINAL AND CHOROIDAL VASCULAR STRUCTURES ARE AFFECTED IN AXIAL SPONDYLOARTHRITIS: AN OPTICAL COHERENCE TOMOGRAPHY STUDY

Berkay Akmaz¹, Fahrettin Akay¹, Dilek Solmaz², Onay Gercik², Gokhan Kabadayi², Idil Kurut², Servet Akar². ¹Izmir Katip Celebi University, Faculty of Medicine, Ophthalmology, Izmir, Turkey; ²Izmir Katip Celebi University, Faculty of Medicine, Rheumatology, Izmir, Turkey

Background: Axial spondyloarthritis (axSpA) is a chronic inflammatory disease that mainly affects axial skeleton. Ocular inflammation is one of the most common extra-articular manifestations of axSpA, mainly form of acute anterior uveitis (AAU). However posterior segment of the eye was rarely evaluated. The inaccessibility of posterior structures like choroid and retina to direct examination led clinicians to use non-invasive imaging technics. Optical coherence tomography (OCT) is an imaging technology

providing, high-resolution, and non-invasive cross-sectional view of micro-spic, anterior and posterior ocular structures.

Objectives: To evaluate the retina and choroidal vascular structures in axSpA patients by using the advantage of OCT and to compare the changes (if any) with healthy control subjects.

Methods: In total 70 (66% male; mean age 39.7 ± 10.4 years) axSpA patients (50 radiographic- and 20 nr-axSpA) and 50 (mean age 41.2 ± 6.2 years) healthy control subjects were included in the analysis. All patients underwent a detailed ophthalmologic examination by the same ophthalmologist. All individuals with significant refractive errors (>3 diopters of spherical equivalent refraction) and intraocular pressure ≥ 21 mmHg were excluded from the analysis. Choroidal thickness (ChT), macula, and the ganglion cell complex (GCC) were measured by spectral domain optical coherence tomography (SD-OCT) by the same experienced operator.

Results: Mean ($\pm$ SD) BASDAI score was 3.6 ± 2.5 , BASFI score was 3.4 ± 2.9 , ASDAS-CRP was 2.6 ± 1.3 in axSpA patients and 14% of them has a history of AAU and 61% ever treated with TNFi agents. There was no significant difference between groups regarding refractive error ($P=0.640$), intraocular pressure ($P=0.815$) and BMI ($P=0.124$) that could affect the OCT measurements. ChT ($P<0.001$) were increased and GCC thickness ($P<0.001$) were decreased in axSpA patients however both layer thicknesses were similar between r- and nr-axSpA patients ($P=0.780$ and $P=0.677$) (Table). History of uveitis was not associated with ChT and GCC. Although GCC was further decreased in TNFi treated patients (105.8 vs 113.3) this difference did not reach significance ($P=0.058$). Education level was associated both ChT and GCC measurement. GCC thickness was also related with BMI and sex in univariate analysis. Other disease related characteristics including the ones related with disease activity were not related with posterior segment measurements.

Conclusion: Our results showed that beside anterior segment inflammation, posterior segment of the eye could be affected in both r- and nr-axSpA patients. Retina and choroidal vascular network forms the posterior segment of the eye. The thinning of GCC which form the inner neural layer of the retina is a good indicative of micro-neurotoxicity in axSpA. Elevation of the ChT may be an important indicator of inflammation.

Table. Demographic features and eye assessment results of study population

Variables	r-axSpA (n=50)	nr-axSpA (n=20)	axSpA (n=70)	Control (n=50)	P*
Age, mean (SD)	41.3 (11.1)	35.8 (7.3)	39.7 (10.4)	41.2 (6.2)	>0.05
BMI, mean (SD)	25.1 (4.3)	26.3 (4.1)	25.5 (4.2)	25.9 (1.3)	>0.05
Education years, mean (SD)	9.1 (4.0)	10.6 (3.6)	9.5 (3.9)	N/A	-
History of AAU, n (%)	6/42 (14.3)	2/16 (12.5)	8/58 (13.7)	N/A	-
TNFi usage, n (%)	32 (64)	11 (55.0)	43 (61.4)	N/A	-
Intraocular pressure, mmHg, mean (SD)	15.0 (2.3)	14.6 (1.9)	14.8 (2.2)	14.8 (2.2)	>0.05
Choroid thickness μ M, mean (SD)	333.3 (68.8)	329.8 (69.8)	332.3 (68.6)	263.3 (26.9)	<0.001
Macula thickness μ M, mean (SD)	255.9 (32.3)	256.1 (16.8)	255.9 (28.6)	262.6 (20.8)	>0.05
GCIPL μ M, mean (SD)	106.9 (8.7)	113.2 (27.2)	108.7 (16.3)	112.7 (7.3)	<0.001

* P between AxSpA and controls.

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AB0713

MAGNETIC: RESONANCE IMAGING AND ULTRASONOGRAPHIC MEASUREMENTS OF THE FEMORAL CARTILAGE THICKNESS IN PATIENTS WITH ANKYLOSING SPONDYLITIS

Fatma Ali, Ayman Darwish, Shereen Refaat, Omnia Adel, Nadia El Ameen. Minia University faculty of medicine, Rheumatology and Rehabilitation, Minia, Egypt

Background: Ankylosing spondylitis (AS) is a progressive inflammatory disease involving cartilaginous structures in the spine and peripheral joints.

Objectives: To examine the role of musculoskeletal ultrasound (MSUS) and magnetic resonance imaging (MRI) in assessing femoral cartilage thicknesses in patients with AS and healthy controls, and to study the correlation between femoral cartilage thicknesses measurements and disease parameters

Methods: Twenty five patients with AS (17 males and 8 females), and twenty five age, sex and BMI matched healthy individuals were included. For all patients assessment of disease activity, spinal mobility, functional limitation and radiological changes were done. Thickness of the femoral articular cartilage was measured by MSUS using a 10-18 MHz linear probe, three mid-point measurements were taken from each knee at the lateral condyle, intercondylar area, and medial condyle. Thickness of the femorotibial articular cartilage was measured by MRI using 1.5 Tesla MR machine.

Results: AS patients had thinner femoral cartilage thickness than the healthy controls at all MSUS measurement sites, with statistically significant differences at medial femoral condyle and intercondylar area in both right and left knees ($p<0.05$). According to MRI examination, AS patients had statistically significant ($p<0.05$) thinner cartilage thickness at all subdivisions of femoral and tibial condyles than the healthy controls. Femoral cartilage thickness measurements either assessed by MSUS or MRI was negatively correlated with age, age at onset of the disease, and measures of disease activity and radiological changes. Positive correlation between ultrasonographic total femoral cartilage thickness and MRI total femoral cartilage thickness was found ($r=0.49$, $p=0.02$).

Conclusion: Patients with ankylosing spondylitis seem to have thinner femoral cartilage thickness than healthy controls. Correlations of knee cartilage thickness (assessed by MSUS and MRI) with demographic data and disease parameters reflect useful value of MSUS and MRI in determining early cartilage loss in AS patients.

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AB0714

BALANCE AND FALLS IN AXIAL SPONDYLOARTHRITIS: A CROSS SECTIONAL STUDY

Kerilyn Brenda Mewes, Betania Longo, Ana Paula Beckhauser de Campos, Juliana Simioni, Thelma Laroca Skare. Hospital Universitário Evangélico Mackenzie, Department of Rheumatology, Curitiba, Brazil

Background: Spondyloarthritis (SpA) patients may suffer of balance loss predisposing them to falls.

Objectives: To study balance impairment and falls in SpA patients and its association with clinical and epidemiological variables, disease activity, functional and metrology indexes.

Methods: Cross sectional study of 55 SpA patients with axial disease. Clinical and epidemiological were collected from the charts. Balance was assessed by Berg Balance Scale(BBS). The following instruments were applied: ASDAS (Ankylosing Spondylitis Disease Activity Score)-ESR, ASDAS-CRP, BASDAI (Bath Ankylosing Spondylitis Disease Activity Index), BASFI(Bath Ankylosing Spondylitis Functional Index), BASMI(Bath Ankylosing Spondylitis Metrology Index) and ASQoL (Ankylosing spondylitis quality of life questionnaire). The number of falls in the last year was collected.

Results: In this sample, 30.9% had high risk of falls by the BBS and 25.4% recalled having at least one fall in the last years. The BBS values were lower in those with white ethnic background($p=0.01$); and smokers($p=0.03$) and with HLA-B27($p=0.03$) and correlated inversely with BASDAI($\rho=-0.28$), ASDAS-ESR($\rho=-0.32$) and ASDAS-CRP($\rho=-0.33$), BASFI($\rho=-0.71$, $p<0.0001$), BASMI($\rho=-0.80$; $p<0.0001$), ASQoL($\rho=-0.57$; $p<0.001$) and age($\rho=-0.50$; $p<0.001$). Multivariate analysis showed that BASFI and BASMI were independently associated with BBS($p=0.02$ and