AB0709

INFLUENCE OF DIETETARY INTAKES ON SPONDYLOARTHRITIS : AN OBSERVATIONAL PROSPECTIVE STUDY

Kathy Nguyen, Pascale Vergne-Salle, Anne-Catherine Fressinaud-Marie, Philippe Bertin. University Hospital Limoges Dupuytren Hospital, Limoges, France

Background: Dysbiosis can be found in inflammatory joint diseases and induces alterations of the protective function of the intestinal barrier (1). Yet intestinal inflammation exists in ankylosing spondylitis, which is as much severe as the disease is active (2). Benefits of diets and their influence on the microbiota diversity and inflammation deserve to be studied in spondyloarthritis.

Objectives: The aim of the study was to investigate the nutritional profile in active spondyloarthritis.

Methods: An observational prospective monocentric study based in a french rheumatology department based in Limoges was conducted between February and July 2018, demographic and disease data were collected, in addition to the treatments and the food frequency questionnaire. Voluntary patients over 18 years of age with spondyloarthritis defined by ASAS classification were included. Patients with a diagnosis of inflammatory bowel disease or a bariatric surgery history were excluded of the study. The primary outcome was the correlation between omega-3, vitamin C, refined sugars, fibers and ultra-processed food intakes and the disease activity assessed by ASDAS CRP and BASDAI scores.

Results: Among 140 patients included, there was no statistically significant difference in omega-3, vitamin C, refined sugars, fibers or ultra-processed food intakes between patients with active spondyloarthritis (BASDAI ≥ 4 or ASDAS CRP $\geq 1,3$) and very active (ASDAS $\geq 2,1$) and patients with unactive disease. The quality of life score and fatigue score were more important in the active and very active disease forms, likewise for the digestive symptoms but there was no link founded in the different nutrients intakes, neither with the associated treatment.

Conclusion: Although our study did not find any nutritional profile in active spondyloarthritis, there was an alteration of quality of life and more digestive symptoms in the active group. Future researches are however required to explore the impact of dietary intakes on the disease activity of spondyloarthritis.

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AB0710

IXEKIZUMAB SIGNIFICANTLY IMPROVES SELF-REPORTED OVERALL HEALTH AS MEASURED BY SF-36 IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS/RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS NAIVE TO BIOLOGICAL THERAPY: 52 WEEK RESULTS OF A PHASE 3 TRIAL

James Cheng-Chung Wei¹, Filip van den Bosch², Jessica A. Walsh^{3,4}, Uta Kiltz^{5,6}, Theresa Hunter⁷, Yan Dong⁷, Ann Leung⁸, David Sandoval⁷, Luis Leon⁷, Vibeke Strand⁹. ¹Chung Shan Medical University Hospital, Taichung City, Japan; ²Ghent University Hospital, Ghent, Belgium; ³University of Utah School of Medicine, Salt Lake City, United States of America; ⁴Veterans Affairs Medical Center, Salt Lake City, United States of America; ⁵Rheumazentrum Ruhrgebiet, Herne, Germany; ⁶Ruhr-Universität Bochum, Bochum, Germany; ⁷Eli Lilly and Company, Indianapolis, United States of America; ⁸Syneos Health, Raleigh, United States of America; ⁹Biopharmaceutical Consultant, Portola Valley, United States of America

Background: Using the Short-Form-36 (SF-36) questionnaire, previous studies have determined that ankylosing spondylitis/radiographic axial spondyloarthritis (AS/r-axSpA) significantly impairs patients' health-related quality of life (HRQoL).¹ Ixekizumab (IXE), a humanized anti-interleukin-17A monoclonal antibody, improves disease signs and symptoms in patients with AS/r-axSpA.²

Objectives: To quantify the effect of 52 weeks of IXE treatment on self-reported HRQoL in patients with active AS/r-axSpA who are naïve to biologic therapy (NCT02696785).

Methods: COAST-V is a randomized, double-blind clinical trial that is active- and placebo-controlled in its first 16 weeks. Enrolled patients were adults with active AS/r-axSpA with ASAS criteria who fulfilled mNY of sacroiliitis (central reading), with a BASDAI and back pain ≥ 4 , and with no prior treatment with biologic agents. Patients were initially randomized 1:1:1:1 to 80 mg IXE every 4 weeks (Q4W) or every 2 weeks (Q2W), adalimumab (ADA), or placebo (PBO) groups. Changes from baseline in SF-36 up to Week 16 were analyzed by mixed model for repeated measures. Changes from baseline in SF-36 for Weeks 36-52 had no model applied. Missing data were imputed by modified baseline observation carried forward (mBOCF).

Results: By Week 4, statistically significant differences in Physical Component Summary (PCS) were observed between PBO and both IXE Q4W and Q2W groups (Figure; $p \leq 0.002$). Further differences in PCS between PBO and IXE groups were observed up to 16 weeks ($p < 0.001$) and maintained through 52 weeks. The change in Mental Component Summary (MCS) was modest (Table). Improvements in all domains were reported at 52 weeks for both the Q4W and Q2W doses of IXE, with the largest improvements observed in the bodily pain domain (Table).

Conclusion: Improvement in self-reported HRQoL in patients with AS/r-axSpA as measured by SF-36 was observed as soon as Week 4 of IXE treatment and maintained for at least 52 weeks.

Figure. SF-36 Physical Component Summary Mean Change from Baseline.

** $p < 0.002$ IXE Q4W vs. PBO; *** $p < 0.001$ IXE Q4W vs. PBO, *** $p < 0.001$ IXE Q2W vs. PBO.

Dotted lines indicate different analyses were performed at Weeks 4-16 compared to Weeks 36-52. For Weeks 4-16, change from baseline was estimated by mixed model for repeated measures. For Weeks 36-52, observed change from baseline is presented with no model applied, and missing data was imputed by modified baseline observation carried forward.

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Table: SF-36 Baseline Scores and Mean Change at Week 52

	IXE Q4W (n=81)		IXE Q2W (n=83)	
	Baseline	Mean Δ at Week 52	Baseline	Mean Δ at Week 52
Physical Component Summary	36.4	8.3	36.6	8.1
Mental Component Summary	50.7	2.2	46.9	4.5
Domains:				
Physical Function	39.2	7.0	38.1	8.0
Role-Physical	39.3	6.9	38.6	6.7
Bodily Pain	36.7	9.7	36.4	9.3
General Health	41.8	4.2	40.2	5.8
Vitality	45.9	6.1	44.9	6.9
Social Functioning	46.2	4.1	42.9	6.0
Role-Emotional	46.2	4.3	43.3	5.0
Mental Health	48.2	2.5	44.4	5.7

SF-36=Short-Form-36 Questionnaire; IXE Q2W=IXE dosed every 2 weeks; IXE Q4W=IXE dosed every 4 weeks; n=number of patients in analysis population; Mean Δ = mean change from baseline value with mBOCF.

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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 = ≥50% improvement from baseline in the Bath Ankylosing Spondylitis Disease Activity Index, CII = Clinically Important Improvement (ASAS change from baseline ≥1.1), MI = Major improvement (ASAS change from baseline ≥2.2 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	IXE Q4W (N=81)	IXE Q2W (N=83)	
mBOCF (intent-to-treat)			
ASAS-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