multinomial logistic regression modelling was used to calculate which BL characteristics were associated with clinical improvements when adjusted for all other BL characteristics.

Results: At screening, male patients had significantly higher median SPARCC SIJ scores compared with female patients [4.83 [range 0.0–48.0] vs 1.5 [0.0–32.0], $P<0.0001$]. At wk48, 69.1% of 194 patients achieved MIC in either SPARCC SIJ scores, ASDAS or both (Q1/3/4, Figure). There was a statistically significant difference in the number of male versus female patients who achieved MIC in both scores (Q4), compared with patients who achieved MIC in only one or neither (Q1–3, Figure) ($P<0.0001$). However, multinomial logistic regression modelling showed that age ($P=0.0358$), BL ASDAS ($P<0.0001$), and screening SPARCC Spine ($P=0.0358$) and SPARCC SIJ ($P<0.0001$) scores, not gender, were significantly associated with achievement of MIC in both SPARCC SIJ and ASDAS at wk48 for the total population (after adjustment for the effects of other variables).

Conclusions: Although BL summaries showed a significant difference in gender across quadrants, the BL SPARCC SIJ score was strongly correlated with gender (male patients had more inflammation). When both were included in a multivariable model, gender was non-significant. Only age, BL ASDAS, and screening SPARCC SIJ and Spine scores were associated with MIC after 48 weeks of etanercept treatment.

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THU0376 REAL-WORLD USE OF SECUKINUMAB WITH AND WITHOUT A LOADING REGIMEN AMONG PATIENTS WITH ANKYLOSING SPONDYLITIS IN THE UNITED STATES: PATIENT PROFILE AND DOSING

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Background: Secukinumab is a fully human anti-interleukin-17 monoclonal antibody approved for the treatment of patients with moderate to severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis (AS), and may be administered with or without a loading regimen of 150 mg at weeks 0, 1, 2, 3 and 4 followed by maintenance dosing every 4 weeks. The dosing pattern of secukinumab in a real-world setting of patients with AS has not been evaluated since its approval in the United States on January 15, 2016.

Objectives: To describe the demographic, clinical and treatment characteristics (loading, dose) of patients with AS who were treated with secukinumab in routine clinical practice in the United States.

Methods: Retrospective data from the Symphony Health Solutions Lx commercial claims database were used to identify AS patients who had ≥ 1 secukinumab treatment between January 15, 2016 and June 30, 2016. Patients eligible for inclusion were ≥ 18 years of age who had the diagnosis of AS and ≥ 1 pharmacy or medical claim in the 12 months prior to their first secukinumab treatment (index date). Patient demographics and secukinumab dosage were examined at the index date. Clinical characteristics, comorbidities and treatment history in the 12 months prior to the index date were identified and presented by use versus no use of a loading regimen of secukinumab.

Results: A total of 152 patients who initiated secukinumab were included in

this study; the mean (SD) age of included patients was 45.3 (11.1) years and 53.9% were female. Of the 152 patients, 119 patients (78.3%) received a loading regimen and 33 (21.7%) did not. Patient demographics, clinical characteristics and treatment history were not significantly different between the two cohorts (Table 1). The majority of patients (65.5%) with loading initiated secukinumab with the 150-mg dose, whereas the majority of patients (60.6%) without loading initiated with the 300-mg dose. More than half of the patients in each cohort received a biologic therapy during the 12-month baseline period (loading, 65.5%; no loading, 51.5%). Other prior treatments included oral corticosteroids (30.3% for both), conventional synthetic disease-modifying antirheumatic drugs (DMARDs) (loading, 31.9%; no loading, 21.2%) and targeted synthetic DMARDs (loading, 4.2%; no loading, 12.1%). The prevalence of comorbidities was similar between the two cohorts, with the most prevalent comorbidities being hypertension (19.1%), rheumatoid arthritis (19.1%) and other skin diseases (18.4%).

Table 1. Demographics, clinical characteristics and treatment history of patients with AS treated with secukinumab with or without a loading dose of 150 mg

	Overall (n = 152)	Loading (n = 119)	No Loading (n = 33)
Age, mean (SD), years	45.3 (11.1)	46.0 (10.8)	42.6 (11.9)
Female, n (%)	82 (53.9)	67 (56.3)	15 (45.5)
Region, n (%)			
South	46 (30.3)	37 (31.1)	9 (27.3)
Northeast	37 (24.3)	29 (24.4)	8 (24.2)
Midwest	36 (23.7)	25 (21.0)	11 (33.3)
West	33 (21.7)	28 (23.5)	5 (15.2)
Index dose, n (%)			
150 mg	91 (59.9)	78 (65.5)	13 (39.4)
300 mg	61 (40.1)	41 (34.5)	20 (60.6)
Physician specialty, n (%)			
Rheumatology	121 (79.6)	94 (79.0)	27 (81.8)
Internal medicine	8 (5.3)	5 (4.2)	3 (9.1)
Treatment history, n (%)			
NSAID	38 (25.0)	27 (22.7)	11 (33.3)
Oral corticosteroid	46 (30.3)	36 (30.3)	10 (30.3)
csDMARD	45 (29.6)	38 (31.9)	7 (21.2)
tsDMARD	9 (5.9)	5 (4.2)	4 (12.1)
Biologic	95 (62.5)	78 (65.5)	17 (51.5)
Etanercept	31 (20.4)	23 (19.3)	8 (24.2)
Adalimumab	30 (19.7)	27 (22.7)	3 (9.1)
Certolizumab	22 (14.5)	19 (16.0)	3 (9.1)
Golimumab	17 (11.2)	13 (10.9)	4 (12.1)
Infliximab	15 (9.9)	12 (10.1)	3 (9.1)
Ustekinumab	3 (2.0)	3 (2.0)	0 (0.0)
Comorbidities, n (%)			
Rheumatoid arthritis	29 (19.1)	21 (17.6)	8 (24.2)
Hypertension	29 (19.1)	24 (20.2)	5 (15.2)
Other skin diseases	28 (18.4)	23 (19.3)	5 (15.2)
Hyperlipidemia	25 (16.4)	19 (16.0)	6 (18.2)
Fatigue	19 (12.5)	13 (10.9)	6 (18.2)
Depression	18 (11.8)	13 (10.9)	5 (15.2)
Cancer	17 (11.2)	12 (10.1)	5 (15.2)
Psoriatic arthritis	17 (11.2)	13 (10.9)	4 (12.1)
Diabetes	10 (6.6)	9 (7.6)	1 (3.0)
Anxiety	8 (5.3)	6 (5.0)	2 (6.1)
Obesity	6 (3.9)	4 (3.4)	2 (6.1)

AS, ankylosing spondylitis; csDMARD, conventional synthetic disease-modifying antirheumatic drug; NSAID, nonsteroidal anti-inflammatory drug; tsDMARD, targeted synthetic disease-modifying antirheumatic drug.

Conclusions: In this retrospective, administrative claims-based study, the majority of patients with AS initiated secukinumab treatment with a loading regimen. Although only the 150-mg dose of secukinumab is approved for the treatment of AS, almost 40% of patients received the 300-mg dose, indicating a need to better understand patient and treatment characteristics for secukinumab in patients with AS. The results of this study provide early insights into real-world use of secukinumab with and without a loading regimen in patients with AS in the United States.

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THU0377 LOW DOSE IL-2 THERAPY CAN RECOVERY TH17/TREG CELL BALANCE IN PATIENTS WITH SPONDYLOARTHRITIS THROUGH INCREASING REGULATORY T CELLS NUMBERS

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Background: The imbalance in the number of Th17 and Treg cells is suggested to be associated with the pathogenesis of SpA. Recent studies have shown that interleukin-23 (IL-23) and Th17 play a crucial role in the pathogenesis of SpA. However the status of CD4+CD25+Foxp3+Treg cells which exert immunoregulatory functions remains to investigate.

Objectives: To explore the status of the immunologic balance between Th17 cells and Treg cells in patients with SPA, and to assess the effect of low dose IL-2 on the peripheral CD4+ T cells.

Methods: Two hundred and two patients, who met the Assessment of Spondyloarthritis International Society (ASAS) criteria were enrolled and given conventional therapy, including Nonsteroidal Anti-inflammatory Drugs (NSAIDs), biological agents, Sulfasalazine, glucocorticoid. Eighty seven patients were not only given conventional therapy, but also injected subcutaneously low-dose IL-2 (50 WIU/day for 5 days). Clinical and laboratory indicators were compared before and after IL-2 treatment. The CD4+ T cells in peripheral blood were measured by multicolor flow cytometry. The side effects were observed in the course of therapy.

Results: The absolute number and ratio of CD4 + CD25 + FOXP3 + regulatory T cells in peripheral blood of patients with SPA was significantly decreased compared with the healthy control group, (25.13 (18.76,37.37) vs. 33.06 (22.87,42.33), $P < 0.001$); Th17/Treg (0.29 (0.18, 0.49) vs. 0.20 (0.15, 0.34), $P = 0.001$). The absolute number of Treg cells increased more than 3-times (22.70 (14.47, 30.10) vs. 67.87 (48.21, 105.82), $p < 0.001$) after 5 days of low-dose IL-2 treatment. Th17/Treg was significantly higher (0.32 (0.18, 0.57) vs. 0.20 (0.15, 0.34), $P < 0.001$) before treatment compared with healthy controls.

Conclusions: The decrease of CD4 + CD25 + FOXP3 + Treg cells might play a key role in the pathogenesis of SpA. Low dose IL-2 therapy can restore and maintain the balance of Th17 and Treg cells by increasing Treg cells numbers selectively. The therapy is safe. More attention should be paid on the long term benefits of low-dose IL-2 therapy in the further research.

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THU0378 IMPACT OF THE ADALIMUMAB PATIENT SUPPORT PROGRAM ON CLINICAL OUTCOMES IN ANKYLOSING SPONDYLITIS: RESULTS FROM THE COMPANION STUDY

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Background: Adalimumab (ADL) is a TNF-alpha inhibitor indicated for various inflammatory autoimmune diseases including ankylosing spondylitis (AS). Patients receiving ADL in Canada are eligible to enroll in the AbbVie Care patient support program (PSP) which provides them with personalized services including ongoing care coach calls (CCC). In a previous study, rheumatology patients enrolled in AbbVie Care receiving CCC demonstrated significantly greater persistence and adherence to ADL than patients that did not receive CCC (no-CCC).

Objectives: The objective of this study was to examine if ADL patients receiving CCC through the ADL PSP had an increased likelihood of achieving controlled disease state as determined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score < 4 compared to those not receiving CCC.

Methods: A longitudinal analysis using de-identified aggregate-level data collected through the AbbVie Care PSP was performed. Probabilistic matching was used to link patient-level records from the ADL PSP database to records from the QuintilesIMS longitudinal prescription transactions database (LRx). Patients were indexed on the date of their first ADL transaction between January 2010 and October 2015. The ADL PSP database included patient measurements of the BASDAI, a measure of disease activity. To be eligible, patients had to have a baseline BASDAI measurement between 90 days before and 30 days after their index date and have had a follow-up BASDAI measurement 6 to 18 months later. Only patients that were confirmed to be persistent on ADL as confirmed through the LRx records were included in the comparison. Controlled disease (BASDAI < 4) at the time of the follow-up BASDAI assessment was compared in patients having received CCC and patients without CCC. Robust Poisson regression was used to estimate the adjusted relative risk (RR) of controlled disease. Analyses were adjusted for patient age group, sex, region, prior biologic use, days lapsed between BASDAI assessments, and baseline disease control status category.

Results: A total of 249 AS patients met eligibility criteria and 123 (49%) of these had received CCC. Of the 249 patients, 184 (74%) had controlled disease (BASDAI < 4) at the follow-up assessment, 98 (80%) in the CCC group and 86 (68%) in the no CCC group. In the multivariable regression analysis, there was a 23% increased likelihood of achieving controlled disease in the CCC group relative to the group without CCC (RR=1.23, 95% confidence interval: 1.06–1.42; p -value =0.0055).

Conclusions: AS patients receiving tailored services through the ADL PSP in the form of care coach calls have an increased likelihood of achieving controlled

disease within 6 to 18 months. These results may help refine interventions aiming at improving clinical outcomes in AS patients.

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THU0379 IMPACT OF TIME SINCE DIAGNOSIS, AGE, AND NUMBER OF PRIOR NON-STEROIDAL ANTI-INFLAMMATORY DRUGS ON 52-WEEK CLINICAL RESPONSE TO ADALIMUMAB IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Ankylosing spondylitis (AS) patients (pts) were found to respond better to TNF inhibitors (TNFi) if treated early in the disease course.¹ The actual disease onset and hence disease duration is not always known. Previously, younger age was found to have the largest positive impact on clinical outcomes following 12 weeks (wks) of adalimumab (ADA) treatment.²

Objectives: The objective of this analysis was to examine the impact of time since diagnosis, age, and number of prior NSAIDs as surrogates for disease duration on clinical outcomes in AS pts from ATLAS trial treated with ADA for 52 wks.

Methods: ATLAS^{3,4} was a phase 3 randomized double-blind placebo (PBO)-controlled trial evaluating the safety and efficacy of originator ADA in pts with active AS who failed NSAID therapy. In this post hoc analysis, pts who received at least one dose of ADA during the PBO-controlled period or open label extension and received prior NSAID(s) at baseline (BL) were categorized by BL: (1) time since diagnosis (< 2 vs ≥ 2 ; < 5 vs ≥ 5 ; < 10 vs ≥ 10 years [y]), (2) age (< 35 , 35–45, and > 45 y), and (3) number of prior NSAIDs (≤ 2 vs > 2). The effect of time since diagnosis, age, and number of prior NSAIDs on AS outcome measures following 52 wks of ADA treatment was examined.

Results: At wk 52, 274 pts had received at least one dose of ADA and had at least one prior NSAID at BL. A majority of pts were ≥ 5 y since AS diagnosis (188 [68.6%]), ≤ 45 y of age (163 [59.5%]), HLA-B27+ (213 [77.7%]), and had ≤ 2 prior NSAIDs (158 [57.7%]). Pts with shorter time since diagnosis were generally younger (late thirties). Across all subcategories, $> 70\%$ of pts were male. The BL disease activity measures were numerically similar across most categories. Following 52 wks of ADA treatment, the proportions of pts achieving ASAS20 and ASAS40 responses were numerically higher and mean decreases in BASDAI and BASFI scores from BL larger in subcategories with shorter time since diagnosis, younger age, and fewer prior NSAIDs (Table). There were significant differences in ASAS40, BASDAI, and BASFI scores between time since diagnosis (< 2 vs ≥ 2 and < 5 vs ≥ 5 y) and age (< 35 vs > 45 y) subcategories.

Table. Clinical Responses Following 52 Weeks of ADA Exposure in Patients Categorized by Time Since Diagnosis, Age, and Prior NSAID(s).

Outcome measure	Time since diagnosis (years)						Age (years)			Prior NSAID(s)	
	< 2 (n=63)	≥ 2 (n=221)	< 5 (n=86)	≥ 5 (n=188)	< 10 (n=150)	≥ 10 (n=124)	< 35 (n=76)	35–45 (n=87)	> 45 (n=111)	≤ 2 (n=158)	> 2 (n=116)
ASAS20, n (%)	39 (73.0)	152 (69.2)	64 (74.4)	129 (68.1)	105 (70.0)	87 (70.2)	58 (76.3)	63 (72.4)	71 (64.0)	115 (72.8)	77 (66.4)
ASAS40, n (%)	35 (68.0)	104 (47.1)	53 (61.6)	86 (45.7)	59 (39.3)	47 (38.2)	47 (61.9)	46 (52.9)	48 (43.2)	86 (54.4)	53 (45.7)
BASDAI, mean (SD) ¹	-4.1 (2.0)	-3.6 (2.0) [*]	-3.9 (2.0)	-3.9 (2.0) [*]	-3.5 (2.0)	-3.7 (2.0)	-3.7 (2.0)	-3.2 (2.0)	-2.8 (2.0) ^{***}	-3.3 (2.0)	-3.0 (2.0)
BASFI, mean (SD) ¹	-2.8 (2.0)	-2.3 (2.0) [*]	-2.7 (2.0)	-2.4 (2.0) [*]	-2.4 (2.0)	-2.1 (1.9) [*]	-2.7 (2.0)	-2.3 (1.9) [*]	-2.0 (2.0) ^{***}	-2.5 (2.0)	-2.0 (2.0)

¹P-values are based on Pearson's Chi-square test for comparison. *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$.

²Change from baseline to week 52.

NSAID = Non-Steroidal Anti-inflammatory drug; ASAS = Assessment of Spondyloarthritis International Society classification criteria; BASDAI = Bath Ankylosing Spondylitis Disease Activity Index; SD = Standard Deviation; BASFI = Bath Ankylosing Spondylitis Functional Index.

Conclusions: Following 52 wks of ADA treatment, shorter time since diagnosis and younger age were associated with greater clinical responses and improvements in disease activity and functionality. Although younger age (< 35 vs > 45 y) had significant positive impact on the clinical outcomes similar to wk 12 results, shorter time since diagnosis (< 2 vs ≥ 2 and < 5 vs ≥ 5 y) was also associated with better 52-wk clinical outcomes. These results suggest that early effective treatment intervention may improve long-term clinical outcomes in AS pts.

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