

Characteristics	AS; n=108	PsA; n=239
Age (Mean±SD)	46.9±12.7	53.4±11.9
Male (%)	62.0	42.7
CRP (mg/L) (Mean±SD)	14.8±22.5	11.8±18.0
Previous NSAID exposure (%)	61.1	24.7
Previous cDMARD exposure (%)	39.8	72.8
Previous bDMARD exposure (%)	68.5	72.8
Lack of efficacy of prev. bDMARD (%)	82.4	85.1

other studies in the phase III program of secukinumab^{1,2}. Major difference is represented by the high number of biological-experienced patients and comorbidities. Potential differences between these real world results and previously obtained phase III results will have to be discussed to assess their impact on patients.

References:

[1] McInnes IB et al. *Lancet*. 2015;386(9999):1137–46.

[2] Baeten D et al. *Lancet*. 2013;382(9906):1705–13.

Disclosure of Interest: U. Kiltz Grant/research support from: AbbVie, Chugai, MSD, Novartis, Pfizer, Roche, UCB, Consultant for: AbbVie, Chugai, MSD, Novartis, Pfizer, Roche, UCB, C. Legeler: None declared, M. Maier-Peuschel Employee of: Novartis, J. Veit Employee of: Novartis, C. Mann Employee of: Novartis, H.-P. Tony Grant/research support from: AbbVie, Astra-Zeneca, BMS, Chugai, Janssen, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi, Consultant for: AbbVie, Astra-Zeneca, BMS, Chugai, Janssen, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi

DOI: 10.1136/annrheumdis-2017-eular.6164

THU0396 EFFICACY OF SWITCHING bDMARDs IN PATIENTS WITH AXIAL SPONDYLOARTRITIS: RESULTS FROM A SYSTEMATIC LITERATURE REVIEW

V. Navarro-Compán¹, E. de Miguel¹, A. Balsa¹, P. Diaz del Campo², J. Gratacós³. ¹Hospital la Paz, IdiPaz; ²Spanish Society of Rheumatology, Madrid; ³Hospital Parc Taulí, Sabadell, Spain

Background: bDMARDs (TNF or IL-17 inhibitors) have been shown to be efficacious in patients with axial spondyloarthritis (axSpA). However, approximately 30–50% of patients who receive a first bDMARD do not respond well. Current practice in these patients is switching to another bDMARD but the scientific evidence for this attitude is sparse.

Objectives: To evaluate the efficacy of switching bDMARDs in patients with axSpA.

Methods: A systematic literature review until February 2016 was performed using Medline, EMBASE and Cochrane databases. Furthermore, abstracts from the previous EULAR and ACR meetings were reviewed. The research question was formulated according to the PICOS method: Population (axSpA patients); Intervention (bDMARD); Outcome (clinical response); and Setting (longitudinal studies with follow-up ≥12 weeks of follow up including data from ≥50 patients). Data was extracted using a form developed for this specific purpose. The quality of the studies was assessed based on CEBM Oxford. Clinical response in patients who switched to a second bDMARD was determined and compared with the one achieved after receiving the first bDMARD (a TNFi in all cases). Results are shown as median (range) and relative frequencies (%).

Results: In total, 7 studies out of 1506 retrieved citations were included. All studies included patients with ankylosing spondylitis (AS). The study design was prospective observational (n=3), retrospective observational (n=2), open-label trial (n=1) and post-hoc analysis from two RCTs (n=1). The level of evidence for all the studies was 4. In these studies, a total of in 4678 patients received a first bDMARD and 1198 patients switched to a second bDMARD (a TNFi in all cases except in 51 patients that switched to secukinumab). Baseline characteristics of patients included in the studies were: 41 (38–44) years old, 67% (64–74) males, 78% (74–89) HLA-B27+ and BASDAI before switching 6.2 (5.3–6.5). The most frequent reason to switch bDMARD was inefficacy, followed by intolerance/adverse events. Median (range) time to assess response after switching was 6 (3–12) months. The criteria to define clinical response were heterogeneous. BASDAI50 was employed in four studies and the percentage of patients who achieved this response after the first and the second bDMARD for each study was: (63% vs 41%), (50% vs 28%), (54% vs 37%), (72% vs 56%), respectively. The response for the other three studies was based on different definitions, being as follows: BASDAI <4 (83% vs 78%), ASAS20 response (67% vs 48%) and retention rate after one year (65% vs 60%). The reason to switch bDMARD (intolerance or inefficacy) was not found as a significant predictor of treatment response in most of the studies. In addition, two studies reported data (n=137 and 11 patients) to evaluate the efficacy of switching to a third bDMARD (TNFi in both cases). The percentage of patients who responded (BASDAI50) to the third TNFi was 30% and 52%, respectively.

Conclusions: In patients with AS who do not respond to a first TNFi, switching to another bDMARD (either a TNFi or secukinumab) is efficacious in a considerable number of patients (30–50%). However, the clinical response after receiving a second bDMARD is lower to the one experienced after the first TNFi. Published data for switching to a third bDMARD is very limited.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.5717

THU0397 SECUKINUMAB PROVIDES SUSTAINED IMPROVEMENTS IN THE SIGNS AND SYMPTOMS OF ACTIVE ANKYLOSING SPONDYLITIS: 3-YEAR RESULTS FROM A PHASE 3 EXTENSION TRIAL (MEASURE 1)

X. Baraliakos¹, A.J. Kivitz², A. Deodhar³, J. Braun¹, J.C. Wei⁴, E.M. Delicha⁵, Z. Talloccy⁶, B. Porter⁶ on behalf of the MEASURE 1 study group.

¹Ruhr-University Bochum, Herne, Germany; ²Altoona Center for Clinical Research, Duncansville; ³Oregon Health & Science University, Portland, United States; ⁴Chung Shan Medical University Hospital, Taichung, Taiwan, Province of China; ⁵Novartis Pharma AG, Basel, Switzerland; ⁶Novartis Pharmaceuticals Corporation, East Hanover, United States

Background: Rapid and sustained improvements in the signs and symptoms of ankylosing spondylitis (AS) have been reported with secukinumab, a fully human anti-IL-17A mAb, over the first 2 years (yrs) in the Phase 3 MEASURE 1 trial.^{1,2}

Objectives: To report efficacy and safety of secukinumab through 3 yrs in an extension trial (NCT01863732) to the core MEASURE 1 trial.

Methods: After the 2-yr core trial, patients (pts) receiving secukinumab 150 or 75mg s.c. were invited to enter a 3-yr extension trial. Efficacy results at Week (Wk) 156 are reported for pts who were originally randomised to secukinumab. Assessments at Wk 156 included ASAS20/40, BASDAI, BASDAI50, SF-36 PCS, ASAS partial remission (ASAS PR) and ASDAS-CRP. Binary and continuous variables used multiple imputation and MMRM estimates, respectively. Analyses by anti-TNF use (naïve/intolerant to or inadequate response [IR]) was pre-specified and reported as observed. Safety analyses included all pts who received ≥1 dose of secukinumab.

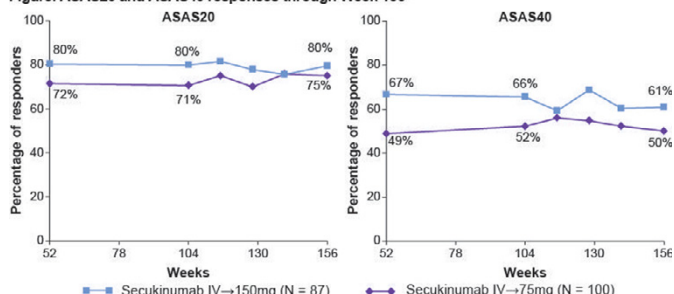
Results: A total of 290/371 pts (78%) completed the 2-yr core trial. Of these, 274 pts entered the extension trial, with 260 completing 156 wks (83/87 pts [95%] in IV→150mg; 95/100 pts [95%] in IV→75mg; 82/87 [94%] pts in placebo→secukinumab). At Wk 156, clinical improvements were sustained across all endpoints (Table, Figure). Similar trends were observed regardless of prior anti-TNF use (Table). Across the treatment period (secukinumab exposure [mean±SD]: 964.3±372.1 days), exposure-adjusted incidence rate with secukinumab for serious infections, Crohn's disease and malignant/unspecified tumours was 1.1, 0.5 and 0.5 per 100 pt-yrs, respectively.

Table 1. Summary of 156-wk efficacy results

	Observed data		Missing data considered ^d	
	Secukinumab IV→150mg (N=87)	Secukinumab IV→75mg (N=100)	Secukinumab IV→150mg (N=87)	Secukinumab IV→75mg (N=100)
ASAS, % response				
ASAS20/40	80/62 ^b	76/50 ^b	80/61	75/50
ASAS PR	27 ^b	14 ^b	27	14
BASDAI				
Baseline, mean±SD	6.1±1.5	6.0±1.5	6.1±1.5 [#]	6.0±1.5 [#]
Mean change from baseline ^c	-3.3±2.4 ^b	-3.0±1.7 ^b	-3.1±0.2	-2.9±0.2
	Secukinumab IV→150mg		Secukinumab IV→75mg	
Analysis by anti-TNF status ^d				
Anti-TNF-naïve ^e	N=70		N=76	
ASAS20/40, % response	80/61		76/48	
Anti-TNF-IR ^e	N=17		N=24	
ASAS20/40, % response	81/63		74/57	

^aMissing data of binary variables were imputed and for continuous variables MMRM estimates are shown. ^bEvaluable data available in n=86 and n=98 pts in the secukinumab IV→150mg and IV→75mg groups, respectively. ^cLeast squares mean±SE for MMRM estimates and mean±SD for observed data. ^dObserved data. ^eEvaluable data available in n=70 and 75 pts (naïve) and n=16 and 23 pts (IR) in the secukinumab IV→150mg and IV→75mg groups, respectively. [#]Observed data provided for reference. IV, pts received secukinumab 10mg/kg i.v. loading at baseline, Wks 2 and 4; N, number of pts in the extension trial.

Figure. ASAS20 and ASAS40 responses through Week 156



Data presented after multiple imputation through Week 156. ASAS20 and ASAS40 responses through Week 104 have been reported previously.² N, number of patients in the extension trial

Conclusions: Secukinumab provided sustained efficacy in signs/symptoms and physical function in pts with active AS over 3 yrs. Secukinumab was well tolerated with a favorable safety profile consistent with that reported previously.^{1,2}

References:

[1] Baeten D, et al. *N Engl J Med* 2015;373:2534–48.

[2] Braun J, et al. *Ann Rheum Dis* 2016;doi: 10.1136/annrheumdis-2016-209730.