SAT0287

WHAT ARE THE ECONOMIC IMPLICATIONS OF ANTI-TNF THERAPY IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS? – RESULTS OF A HEALTH INSURANCE CLAIMS DATA ANALYSIS

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Background: Tumour necrosis factor (TNF)- α inhibitors are an effective but rather expensive treatment option in axial spondyloarthritis (axSpA) patients who fail conventional treatment.

Objectives: The aim of this study was to analyse the changes in healthcare costs and resource utilisation after initiation of TNF- α inhibitors in patients with axSpA.

Methods: Data of patients with axSpA newly exposed to TNF- α inhibitors between January 1, 2011 and December 31, 2015 were studied by using health insurance claims data in Germany. Resource utilisation, direct healthcare costs and productivity costs were assessed. Direct healthcare costs comprised costs for outpatient care (i.e., visits to physicians, laboratory visits, non-physician visits [e.g., visits to physical therapists], emergency department visits, outpatient hospital services, and aids [e.g., walkers]), costs for inpatient care (i.e., inpatient admissions) and costs for pharmacotherapy. Productivity costs comprised costs due to absence from paid work and were calculated using the friction cost method (FCM) and the human capital approach (HCA). Costs and resource utilisation were analysed the year before (baseline period) and the year after (follow-up period) initiation of TNF- α inhibitors.

Results: Data from 1452 persons were included in the analyses; mean age was 44.6 years and 47.9% were female. AxSpA-related pharmacotherapy use (non-steroidal anti-inflammatory drugs [NSAIDs], non-opioid analgesics, opioid analgesics, systemic steroids, local steroids and conventional synthetic disease-modifying anti-rheumatic drugs [csDMARDs]) and admissions to hospital decreased significantly in the follow-up period compared to the baseline period. However, due to anti TNF- α therapy, mean direct healthcare costs increased from € 4494 per patient in the baseline period to € 26 473 per patient in the follow-up period. Mean total costs increased from € 8072 to € 29 959 using the HCA and from € 6377 to € 28 162 using the FCM (Table). Excluding costs for anti-TNF therapy, total costs decreased by 15% to € 6876 or by 20% to € 5080 based on whether the HCA or the FCA was used.

Abstract SAT0287 – Table 1. Mean costs per patient before and after initiation of TNF- α inhibitors in axial spondyloarthritis (n=1,452).

	Baseline period mean $\pm$ SD	Follow-up period mean $\pm$ SD	P-value
Outpatient care*, €	1,402 $\pm$ 1,008	1,381 $\pm$ 1,054	0.0285
Hospital admissions*, €	1,890 $\pm$ 3,681	1,134 $\pm$ 3,558	<0.0001
with diagnosis of axSpA*	612 $\pm$ 1582	136 $\pm$ 714	<0.0001
Pharmacotherapy, €	1,201 $\pm$ 2,939	23,957 $\pm$ 5,480	<0.0001
excluding anti-TNF therapy	1,201 $\pm$ 2,939	875 $\pm$ 1,721	<0.0001
NSAIDs	130 $\pm$ 159	83 $\pm$ 151	<0.0001
non-opioid analgesics	21 $\pm$ 77	12 $\pm$ 46	<0.0001
opioid analgesics	118 $\pm$ 517	123 $\pm$ 564	0.3352
systemic steroids	23 $\pm$ 52	17 $\pm$ 54	<0.0001
local steroids	1 $\pm$ 6	1 $\pm$ 4	0.0091
csDMARDs	159 $\pm$ 366	97 $\pm$ 278	<0.0001
Absence at work, HCA, €	3,578 $\pm$ 7,211	3,486 $\pm$ 7,896	0.0458
Absence at work, FCM, €	1,883 $\pm$ 2,943	1,690 $\pm$ 2,934	0.0021
Total costs, HCA, €	8,072 $\pm$ 9,734	29,959 $\pm$ 10,679	<0.0001
excluding anti-TNF therapy	8,072 $\pm$ 9,734	6,876 $\pm$ 9,626	<0.0001
Total costs, FCM, €	6,377 $\pm$ 6,401	28,162 $\pm$ 7,609	<0.0001
excluding anti-TNF therapy	6,377 $\pm$ 6,401	5,080 $\pm$ 5,813	<0.0001

Values are presented as mean $\pm$ standard deviation. P-values were assessed using Wilcoxon signed-rank tests. Total costs per patient were calculated as the sum of the domains outpatient care, hospital admissions, pharmacotherapy and absence at work.

TNF, Tumour Necrosis Factor; NSAIDs, Nonsteroidal Anti-Inflammatory Drugs; csDMARDs, conventional synthetic Disease-Modifying Anti-Rheumatic Drugs; HCA, Human Capital Approach; FCM, Friction Cost Method; SD, standard deviation.

* excluding costs for pharmacotherapy.

Conclusions: Overall resource utilisation decreased after initiation of TNF- α inhibitors. The rise in pharmacotherapy costs driven by anti-TNF agents is accompanied by significantly lower costs for outpatient and inpatient care, as well as significantly lower productivity costs. However, the effect of TNF-blocker therapy on

the patient's disease activity, function or quality of life could not be assessed in this analysis.

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SAT0288

SECUKINUMAB DEMONSTRATES RAPID AND SUSTAINED EFFICACY IN ANKYLOSING SPONDYLITIS PATIENTS WITH NORMAL OR ELEVATED BASELINE CRP LEVELS: POOLED ANALYSIS OF TWO PHASE 3 STUDIES

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Background: Elevated baseline (BL) CRP levels is one of the predictors of treatment response in patients (pts) with active AS.¹ The relationship between BL CRP levels and the treatment response to IL-17A inhibition has not been assessed in AS pts thus far.

Objectives: This *post-hoc* analysis assessed the response to secukinumab (SEC) treatment in AS pts with normal or elevated BL CRP from the phase 3 MEASURE 1 and MEASURE 2 studies over 3 years.

Methods: The study designs of MEASURE 1 and 2 have been reported.² This analysis pooled data from all pts with available BL CRP levels who received subcutaneous (s.c.) SEC 150 mg (approved dose; n=197) or placebo (PBO; n=195). Efficacy endpoints included ASAS20/40, BASDAI, BASDAI50, ASDAS inactive disease, and ASAS partial remission (PR) stratified by normal (<5 mg/L) and elevated ($\geq$ 5 mg/L) BL CRP; elevated BL CRP group was further subdivided into a range of elevated CRP levels: >5–10, >10–15, >15 mg/L. Data are presented as non-responder imputation (NRI) at Week (Wk)16 and multiple imputation (MI) at Wk156 for binary variables and mixed-effect model repeated measure (MMRM) at Wks 16 and 156 for continuous variables.

Results: Overall, 36.5% (143/392) of pts with normal CRP and 63.5% (249/392) of pts with elevated BL CRP were included in the pooled analysis. BL characteristics were balanced across normal and elevated BL CRP groups.³ At Wk16, efficacy endpoints were improved with SEC 150 mg vs PBO in pts with normal or elevated BL CRP.³ Results were consistent across all levels of elevated BL CRP with a trend for greater improvement in pts with more elevated CRP (Table). Improvements were sustained or further improved at Wk156 in all groups (Table).

Abstract SAT0288 – Table 1. Summary of Clinical Efficacy

		Normal BL CRP (<5mg/L)		Elevated BL CRP					
		SEC (N=72)	PBO (N=71)	SEC (N=38)	PBO (N=31)	SEC (N=19)	PBO (N=31)	SEC (N=68)	PBO (N=62)
Clinical outcomes	Wk								
ASAS20, %	16	56.9 ^b	28.2	42.1	32.3	68.4 ^b	29.0	73.5*	27.4
	156	61.3	–	65.0	–	82.8	–	85.0	–
ASAS40, %	16	34.7 ^c	7.0	31.6	16.1	42.1	22.6	48.5*	11.3
	156	42.4	–	50.0	–	76.4	–	67.9	–
BASDAI, LS mean change from BL	16	-2.2 ^c	-1.0	-1.5	-0.7	-2.8 ^c	-0.6	-2.8*	-0.6
	156	-2.7	–	-2.8	–	-3.6	–	-3.7	–
BASDAI50, %	16	27.8 ^b	7.0	34.2	19.4	42.1 ^b	6.5	41.2*	8.1
	156	40.4	–	56.1	–	75.5	–	58.5	–
ASDAS inactive disease, %	16	19.4 ^c	4.2	21.1	6.5	26.3	0	8.8	1.6
	156	28.9	–	28.5	–	16.9	–	15.1	–
ASAS PR, %	16	12.5	2.8	23.7 ^c	3.2	15.8	3.2	11.8	4.8
	156	14.4	–	34.6	–	33.4	–	30.2	–

*P<0.0001, ^bP<0.001, ^cP<0.01, ^dP<0.05 vs PBO; NRI/MMRM data presented at Wk16. MI and MMRM presented at Wk156 included n=56 in normal and n=32, 18, and 53 in >5 to 10, >10 to 15, and >15mg/L elevated CRP groups, respectively. Data included pts (87/125) continuing in the extension trial for MEASURE 1 and all pts for MEASURE 2 at Wk156. LS, least squares; N, number of pts with available BL CRP at Wk16; n, number of pts at Wk156.

Conclusions: SEC 150 mg demonstrated sustained efficacy through 3 years in AS patients with both normal and elevated CRP levels, with an increased effect in elevated CRP patients.

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SAT0289

LONG-TERM EFFECTS OF TNF-ALPHA INHIBITORS ON BONE MINERAL DENSITY AND THE INCIDENCE OF VERTEBRAL FRACTURES IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Ankylosing Spondylitis (AS) is not only characterised by pathological bone formation leading to ankylosis, but also by bone loss which may lead to vertebral fractures (VFX). TNF-alpha inhibitors (TNFi) have proven to be effective in blocking the inflammatory process. A few studies also showed an increase of Bone Mineral Density (BMD) in AS patients treated with TNFi¹⁻³; however, the incidence of VFX after two years of treatment was increased.³⁻⁴

Objectives: To evaluate the long-term effect of TNFi on BMD and the incidence of VFX in patients with AS.

Methods: Consecutive TNFi naive AS patients (who fulfilled the Modified New York criteria) were included. Patients were recruited from the VUmc and Reade and were treated with TNFi for 4 years. BMD at hip and lumbar spine (LS) were measured at baseline and after 4 years. T-scores were categorised as 'normal BMD', 'osteopenia' and 'osteoporosis', based on the WHO osteoporosis criteria.⁵ The incidence of VFX was determined by two observers using the Genant method.⁶

Results: In total, 107 AS patients with complete datasets (68.2% male) were included. The mean age was 42.6 years and the disease duration (time since diagnosis) was 11.0 years. The use of steroids or osteoporosis prophylaxis varied respectively between 0.9% and 2.8%. At baseline 40.1% of the patients had a decreased BMD of the hip and 40.2% of the spine, of whom 27 patients (26%) had both a decreased hip BMD as well as a decreased lumbar BMD. The BMD of spine and hip improved after 4 years of TNFi treatment (table 1). In 13 patients (12.1%), 14 VFX were observed both at baseline and after 4 years of TNFi-treatment, 26 VFX were observed in 21 patients.

After 4 years, 4 out of 21 patients with ≥ 1 VFX had a decreased BMD at hip and lumbar spine whereas the other 17 patients had a normal BMD. The majority of VFX was localised in the mid or lower thoracic spine.

Table 1 BMD measurement in spine and hip of 107 AS patients treated with TNFi.

	Baseline*	After 4 years of TNFi**
Osteopenia LS	34 (31.8)	25 (23.4)
Osteoporosis LS	9 (8.4)	2 (1.9)
Abnormal BMD LS	43 (40.2)	27 (25.3)
Osteopenia total hip	39 (36.4)	31 (29.0)
Osteoporosis total hip	4 (3.7)	3 (2.8)
Abnormal BMD total hip	43 (40.1)	34 (31.8)
Patients with VFX	13 (12.1)	21 (19.6)
Total number of VFX	14	26

* 1 patient with spondylolysis; 4 patients with a total hip replacement

** 2 patients with spondylolysis; 5 patients with a total hip replacement

LS: lumbar spine, Abnormal BMD = osteopenia and/or osteoporosis according to WHO guideline⁵

Vertebral fractures (VFX) are presented in number of patients with a VFX and the actual prevalence of VFX. Outcomes are presented in n (%)

* p < 0.05, ** p < 0.001

Conclusions: The percentage of relatively young AS patients with a decreased BMD at baseline of the hip and lumbar spine was high (40%). After 4 years of TNFi-treatment, the BMD of the lumbar spine improved in 14.9% of the patients and of the hip in 8.3% of the patients. At baseline, 12% of the patients had vertebral fractures which increased to 21% after 4 years of treatment. A normal population of 1984 individuals above 50 years showed a prevalence of 8.9% osteoporotic spinal fractures.⁷ Probably, the start of treatment with TNFi at an earlier stage of the disease might prevent the onset of fractures in AS.

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SAT0290

CANADIAN ADALIMUMAB POST-MARKETING OBSERVATIONAL EPIDEMIOLOGICAL STUDY ASSESSING THE EFFECTIVENESS OF ADALIMUMAB VS. NON-BIOLOGIC DMARDS IN ANKYLOSING SPONDYLITIS (COMPLETE-AS): 12-MONTH EFFECTIVENESS DATA

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Background: COMPLETE-AS is an ongoing Canadian observational study of anti-TNFα naïve adults with active AS per the judgment of the treating physician, who require change in current AS treatment to either¹ a subsequent NSAID or non-biologic disease modifying antirheumatic drug (nbDMARD group), or² to adalimumab (ADA group).

Objectives: The aim of this analysis was to describe and compare the baseline demographic and disease parameters of patients in the nbDMARD and ADA groups and to compare the 12 month effectiveness of the two treatment methods.

Methods: In the current analysis patients enrolled between July/2011 – Jun/2016 were included. Outcome measures analysed were extra articular manifestations (EAM 1: IBD, psoriasis, uveitis, enthesitis; EAM 2: IBD, uveitis, enthesitis), disease activity (BASDAI), functional status (BASFI), and quality of life (QoL; SF-12). Between-group differences in baseline parameters were assessed with the Chi-square test for categorical variables and the independent samples t-test for continuous variables. Baseline-adjusted changes in BASDAI and BASFI over time were compared between the two groups using linear mixed models.

Results: A total of 609 patients (nbDMARD n=177, ADA n=432) were included in the current analysis. No significant differences in baseline demographics were observed between the two groups. However, at baseline, patients initiating ADA were more likely to be unemployed (38% ADA vs. 27.1% nbDMARD, p=0.009), had higher mean BASDAI (6.4 vs. 5.0; p<0.001) and BASFI (5.5 vs. 3.7; p<0.001) scores, and worse QoL (SF-12 PCS: 24.4 vs. 24.7, p=0.002) at baseline. The baseline prevalence of EAMs was comparable between the two groups (EAM 1: 34.7% vs. 31.6%, p=0.454; EAM 2: 25.9% vs. 22.6%, p=0.381). However, IBD was more common among patients initiating ADA treatment (9% vs. 4.5%, p=0.062).

After 12 months of treatment the prevalence of EAMs decreased significantly in the ADA group (EAM 1: p=0.004; EAM 2: p=0.033) but not in the nbDMARD group. After adjusting for baseline values, patients treated with ADA had numerically lower BASDAI score (least square means – LSM: 3.7 vs. 4.3, p=0.171) significantly lower BASFI score (2.9 vs. 3.6, p=0.031) scores, and comparable SF12-