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THU0360 IMPROVEMENTS IN SLEEP PROBLEMS AND PAIN IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS TREATED WITH INTRAVENOUS GOLIMUMAB: 28-WEEK RESULTS OF THE PHASE III GO-ALIVE TRIAL

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Objectives: To investigate the effect of intravenously administered (IV) Golimumab (2 mg/kg), an anti-TNFα monoclonal antibody, on sleep problems, total back pain, and night back pain in adult patients (pts) with active Ankylosing Spondylitis (AS).
Methods: GO-ALIVE is a Phase 3, multicenter, randomized, double-blind, placebo-controlled trial. Pts (aged ≥18 years) had a diagnosis of definite AS (per modified New York criteria) and BASDAI ≥4, total back pain visual analogue scale (VAS) ≥4, and CRP ≥0.3mg/dL. At baseline, 208 pts were randomized to IV golimumab 2mg/kg (N=105) at Wks 0, 4, and every 8 wks or placebo (N=103) at Wks 0, 4, and 12, with crossover to IV golimumab at Wk 16 and through Wk 52. Sleep problems were assessed using the Medical Outcomes Study Sleep Scale (MOS-SS, range 0–100), a generic instrument designed to assess six dimensions of sleep, including 1) Sleep disturbance, 2) Somnolence, 3) Sleep adequacy, 4) Snoring, 5) Awaken short of breath or headache, and 6) Quantity of sleep/optimal sleep during the past 4 wks. The six dimensions are also used to generate the composite Sleep Problems Index. An increase in score from baseline represents improvement. Total back pain and night back pain over the past wk were assessed using VAS (0–10 cm; 0=no pain, 10=most severe pain). Wk 28 results are presented here. Unadjusted p-values of least square mean differences (LSMD) between treatment groups were based on analysis of covariance (ANCOVA) controlling for prior anti-TNF therapy.
Results: Mean changes in MOS-SS Sleep Index and 6 subscales are presented in Table 1. Improvement ($p<0.05$) in the MOS-SS sleep index and 4 subscales at Wk 8 was observed in golimumab compared to placebo, and in the sleep index and 4 subscales at Wk 16. Improvements from baseline to Wks 8 and 16 in pts' assessment of total back pain (cm) were greater ($p<0.001$) in golimumab than placebo (-2.70 vs -0.86 and -3.15 vs -1.15, respectively), and after placebo crossed over to golimumab, the differences diminished at Wk 28 (-3.14 vs -3.34, respectively). Improvements at Wks 8 and 16 from baseline in pts' assessment of night back pain (cm) were also greater ($p<0.001$) in golimumab than placebo (-3.03 vs -0.87 and -3.44 vs -0.85, respectively), and differences diminished at Wk 28 (-3.47 vs -3.42, respectively). Changes from baseline in all subscales of MOS-SS were correlated (Spearman correlations ranging between -0.10 and -0.45) with total back pain (TBP) and night back pain (NBP) at Wks 8, 16, and 28 (p values <0.05), with the exception of Snoring and both TBP and NBP at Wk 16. Change in NBP was associated with change in Sleep Problem Index at all 3 time points (p=0.002, p=0.001, and p=0.031, respectively). In the general linear model, most of the association between change in TBP and change in Sleep Problem Index was explained by the association between change in NBP and change in Sleep Problem Index.

Table 1. Summary of mean (standard deviation) changes in MOS-SS and its subscales.

	GLM	PBO	GLM	PBO	GLM	PBO*
MOS-SS	N=104	N=102	N=104	N=102	N=104	N=102
	Week 8		Week 16		Week 28	
Mean (SD) change from baseline in:						
Sleep problems index:	5.10 (7.86) p<0.001	1.72 (7.36)	6.63 (7.18) p<0.001	2.49 (8.16)	6.58 (8.05)	5.88 (8.29)
Sleep disturbance:	4.44 (8.81) p=0.001	1.32 (7.09)	6.08 (7.76) p<0.001	2.37 (7.88)	6.32 (8.42)	5.07 (8.17)
Somnolence:	3.37 (7.34) p=0.016	1.21 (8.58)	5.27 (7.05) p<0.001	1.47 (8.18)	4.82 (7.87)	4.54 (7.81)
Sleep adequacy:	3.12 (8.24) p=0.037	1.80 (8.59)	4.14 (8.36) p=0.012	2.09 (8.93)	3.73 (7.88)	5.75 (10.15)
Snoring:	1.97 (7.71) p=0.30	0.82 (6.58)	1.24 (7.72) p=0.98	1.04 (6.24)	1.90 (7.39)	0.89 (7.28)
Awaken short of breath or headache:	4.64 (12.44) p=0.043	1.15 (10.02)	4.08 (12.26) p=0.20	1.50 (11.20)	4.19 (12.50)	3.00 (11.21)
Quantity of sleep/optimal sleep:	0.13 (0.57) p=0.43	0.10 (0.52)	0.13 (0.59) p=0.019	0.01 (0.57)	0.16 (0.56)	0.19 (0.56)

*At Wk28. PBO has crossed over to GLM

Conclusions: Adult pts with active AS treated with IV golimumab showed improvements in sleep problems, total back pain, and night back pain. Night back pain improvement was associated with improvement in sleep problems.
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THU0361 PRESCRIPTION PATTERNS OF BIOLOGICAL DISEASE MODIFYING DRUGS AND BIOSIMILARS IN ANKYLOSING SPONDYLITIS – A COLLABORATION BETWEEN BIOLOGICAL REGISTERS IN THE FIVE NORDIC COUNTRIES

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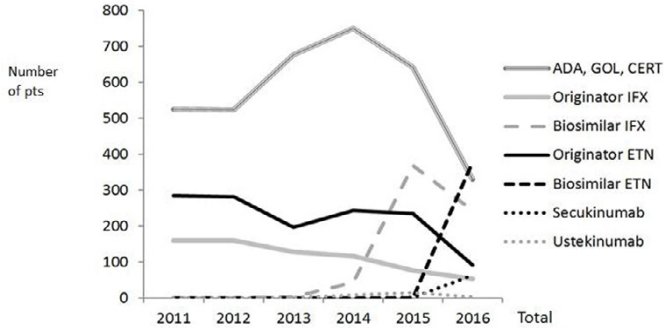
Background: Large-scale real life observational cohorts are needed to study effectiveness and early signals of rare safety issues of new biological disease modifying drugs (bDMARDs) and biosimilars (bsDMARDs) in ankylosing spondylitis (AS). Combining data from biological registries would facilitate this. The Nordic countries have several similarities that would justify such aggregated analyses including similar health care systems with universal access to population based health care, availability of b/bsDMARDs through a tax-paid system and the registration of use and effectiveness of bDMARDs in inflammatory diseases in a prospective manner in drug registries.
Objectives: To explore the prescription patterns of old (TNF-inhibitors) and newer bDMARDs (secukinumab, ustekinumab) including bsDMARDs (SB4, CT-P13) over time in AS in the Nordic countries in order to illustrate the potential of a common Nordic collaboration.
Methods: Data regarding the numbers of AS patients (pts) (ICD10 code M45) who initiated bDMARD treatment (irrespective of treatment course number) during the period 2011–2016 were collected from the Nordic rheumatologic biological registries SRQ (Sweden), NOR-DMARD (6 Norwegian treatment centres), DANBIO (Denmark), ROB-FIN (Finland, 2011–2015) and ICEBIO (Iceland).
Results: In total, 6,610 bDMARD treatment initiations were identified (Sweden 3654, Norway 1078, Denmark 782, Finland 789, Iceland 307).
The prescription patterns of bDMARDs changed substantially over time. In 2016, the number of pts initiating a bsDMARDs exceeded those starting an originator bDMARD (figure). Few patients were treated with ustekinumab (Denmark <10 pts, Finland <10, Sweden 26) and secukinumab (Denmark <10 pts, Sweden 57).

Figure. The 5 Nordic countries, total number of AS patients initiating bDMARD per year



	2011	2012	2013	2014	2015	2016	Total
ADA, GOL, CERT	526	523	677	751	642	330	3449
Originator IFX	160	160	128	116	76	54	694
Biosimilar IFX	0	0	4	44	369	244	661
Originator ETN	285	282	197	244	235	91	1334
Biosimilar ETN	0	0	0	0	0	378	378
Secukinumab	0	0	0	0	1	64	65
Ustekinumab	0	0	1	9	15	4	29
Total	971	965	1007	1164	1338	1165	6610

ADA: Adalimumab, GOL: Golimumab, CERT: Certolizumab Pegol , IFX: Infliximab, ETN: Etanercept

Conclusions: The use of bsDMARDs in AS is rapidly increasing. The use of drugs with new modes of action is still low, which illustrates the need for collaboration across countries to provide real life data with sufficient power for new innovative therapies in the future. The Nordic rheumatologic registries represent a unique