Conclusions: A multidisciplinary approach can improve in the therapeutic management and outcome (e.g. disease activity measures) of eSpA patients. bDMARD use paralleled an improvement in disease measures and confirmed a good safety profile.

Disclosure of Interest: None declared

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SAT0267

EFFICACY AND SAFETY OF BCD-055, PROPOSED INFlixIMAB BIOSIMILAR, COMPARED TO INFlixIMAB: 54-WEEK RESULTS FROM ASART-2 PHASE 3 CLINICAL STUDY

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Background: Non-inferiority of BCD-055 in direct comparison to infliximab originator after 30 weeks of treatment in patients with ankylosing spondylitis (AS) was shown previously¹. Here we present 54 week safety and efficacy data in ITT population from international double-blind randomised ASART-2 clinical trial.

Objectives: To compare BCD-055, proposed infliximab biosimilar and infliximab originator in terms of efficacy and safety in patients with AS.

Methods: Adult patients (n=199) aged 18–65 years, with active AS (BASDAI>4) received 5 mg/kg of BCD-055 (n=132) or infliximab (n=67) IV on w0, w2 and w6 and then every 8 w until w54. The results of the primary endpoint assessment (ASAS20 at w30) were presented earlier¹. Secondary endpoints were proportion of patients, achieved ASAS20/40, and mean change from baseline in BASDAI, BASMI, BASFI, MASES, SF36 scores, chest excursion and TJC⁴⁴ at w54. Rate of AEs and proportion of patient with ADA to infliximab in both groups were also evaluated.

Results: The proportions of patients achieved ASAS20/ASAS40 were similar in both study groups at w54 (Abstract SAT0267 – figure 1). Improvement in AS symptoms showed similar dynamics in both groups: significant decrease in AS activity (BASDAI) and improvement in other secondary endpoints has developed within the first 14 weeks of treatment in both study groups and remained at achieved level until w54. The magnitude of changes of all evaluated parameters did not differ between groups.

No statistically significant differences in rates of AEs were found between study groups (table 1). Most common reported AEs were infections, hematologic and vascular disorders, hypersensitivity reactions. Formation of ADA to infliximab was detected with similar frequency in both groups.

Abstract SAT0267 – Table 1. 54 w safety data

	BCD-055, n (%)	Infliximab, n (%)	p value
Any AE/SAE	82 (62.12)	43 (64.18)	0.898
Any SAE	7 (5.30)	5 (7.46)	0.376
Therapy-related AE/SAE	40 (30.30)	26 (38.81)	0.296
Therapy-related SAE	5 (3.79)	4 (5.97)	0.489
Any SAE/AE grade 3–5	18 (13.64)	11 (16.42)	0.754
Therapy-related AE grade 3–5	11 (8.33)	7 (10.45)	0.818
Treatment withdrawal due to SAE/AE	11 (8.33)	7 (10.45)	0.818
Deaths	1 (0.76)	0 (0)	1.000
ADA positive	27 (21.26)	13 (20.63)	0.920
ADA positive, confirmed by neutralisation assay	4 (3.15)	4 (6.35)	0.443

Abstract SAT0267 – Figure 1. Proportion of patients achieved ASAS20 at weeks 14, 30 and 54 (%; 95%CI).

Conclusions: The 54 week results supports previously confirmed similar efficacy and safety of BCD-055, proposed infliximab biosimilar, and infliximab originator in patients with active AS. At all evaluated time points the efficacy as well as rate of AEs/SAEs did not differ between BCD-055 and infliximab originator groups.

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SAT0268

SECUKINUMAB DEMONSTRATES LOW RADIOGRAPHIC PROGRESSION AND SUSTAINED EFFICACY THROUGH 4 YEARS IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

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Background: The MEASURE 1 core trial reported improved signs and symptoms of ankylosing spondylitis (AS) with secukinumab, a fully human anti-interleukin-17A monoclonal antibody.¹

Objectives: To assess efficacy, including imaging outcomes, and safety from the MEASURE 1 extension trial (NCT01863732) up to 4 years.

Methods: Patients (pts) had completed 104 wks (2 years) in the core study with SC secukinumab 150 (IV→150 mg) or 75 mg (IV→75 mg) every 4 wks, following IV loading to Wk4, or placebo to Wk16/24. Efficacy data at Wk208 are reported for pts originally randomised to secukinumab 150 mg (approved dose). Lateral cervical and lumbar spine radiographs were assessed with the modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS), and MRIs with the Berlin SI joint total oedema score and Berlin spine score (derived from ASpi-MRI-a results). Images were evaluated by 2 central readers blinded to treatment/visit; mean scores were used. Descriptive statistics on observed/imputed data are provided.

Results: Of the 274 pts enrolled in this extension study, 89.7% (78/87) originally assigned to secukinumab 150 mg completed 208 wks. Δ mSASSS (mean ±SD) from baseline (BL) to Wk208 was numerically lower with secukinumab 150 mg (1.2±3.91) vs 75 mg (1.7±4.70). No definite radiographic progression (Δ mSASSS from BL <2) was seen in 79% of pts on secukinumab 150 mg over 208 wks (figure 1). Mean Δ mSASSS at Wk208 was numerically higher in males, and in pts with

BL syndesmophytes or elevated BL hsCRP. Reductions from BL in the Berlin SI joint oedema and Berlin spine scores were seen with secukinumab 150 mg. Sustained efficacy in signs/symptoms was seen through 208 wks (Table). Exposure-adjusted incidence rates per 100 pt-yrs (total exposure [mean $\pm$ SD]=3.4 $\pm$ 1.44 years) were: serious infections (1.0), IBD (0.7), uveitis (1.8) and malignant/unspecified tumours (0.5).

Abstract SAT0268 – Table 1. Efficacy at Wk208

	Secukinumab IV $\rightarrow$ 150 mg (n=87)
mSASSS^{a,b}	
BL (n=71 with X-rays at BL and Wk208)	8.8 $\pm$ 16.23
Δ BL to Wk208	1.2 $\pm$ 3.91
Δ BL to Wk104/ Δ Wk104 to 208 ^d	0.5 $\pm$ 1.69/0.8 $\pm$ 3.34
MRI^{a,b}	
Berlin SI joint total oedema score, Δ BL to Wk104/ Δ BL to Wk208	-2.3 $\pm$ 3.06 ¹⁸ /-1.6 $\pm$ 3.03 ²²
Berlin spine score, Δ BL to Wk104/ Δ BL to Wk208	-0.9 $\pm$ 2.17 ¹⁸ /-0.6 $\pm$ 2.01 ²²
Clinical efficacy	
ASAS20/40 ^e	76.4/58.0
BASDAI, ^f Δ from BL	-3.3 $\pm$ 0.23
ASDAS inactive disease ^g	27.6
BASFI/BASMI, ^h Δ from BL	-2.9 $\pm$ 2.39 (80)/-0.5 $\pm$ 1.12 (76)

n, no. of pts assessed; N, total no. of pts in extension trial

^aRadiographs/MRIs taken at BL and Wk104 were re-read for pts completing Wk208 of treatment; ^bMean $\pm$ SD (n) for observed data; ^cBased on n=67 pts with X-rays at BL, Wk104 and Wk208 and BL mSASSS of 8.01 ± 15.29 and 9.01 ± 16.77 , calculated from matched vertebral edges at BL and Wk104, and BL and Wk208, respectively; ^e% pts estimated using multiple imputation; ¹⁸Least-squares mean $\pm$ standard error for MMRM estimates

Conclusions: Secukinumab 150 mg showed numerically lower radiographic progression vs 75 mg at 4 years. Secukinumab also demonstrated sustained efficacy on signs and symptoms, and MRI outcomes and a consistent safety profile.¹

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SAT0269

THE EFFECT OF BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS IN TARGETING DISEASE REMISSION IN AXIAL SPONDYLOARTHRITIS (AXSPA): A SYSTEMATIC LITERATURE REVIEW

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Background: The treat-to-target concept is currently recommended in axSpA management and remission is the main objective of treatment. Although consensual definitions of remission are lacking, most authors assume remission as a state of inactive disease or, alternatively, of low disease activity, as a near concept. In current practice, ASAS-Partial Remission (ASAS-PR) and ASDAS-Inactive Disease (ASDAS-ID) scores have gained wide acceptance as clinical remission-like definitions.

Objectives: In this review we assessed the efficacy of different biologic disease-modifying anti-rheumatic drugs (bDMARD) in achieving ASAS-PR or/and ASDAS-ID as remission-like primary outcomes. Data from randomised controlled trials (RCT) conducted in radiographic axSpA (r-axSpA) and non-radiographic axSpA (nr-axSpA) patients were included.

Methods: A systematic literature review was performed using the MEDLINE database (August 17 2017) with the filters “published in the last 10 years” and “humans”. The PICO (P, population; I, intervention; C, comparison; O, outcome) concept was used to perform the analysis according to: Patients – adults (>18 years old) with r-axSpA or nr-axSpA; Intervention – any bDMARD regardless of formulation or duration; Comparison – placebo and/or any different drug; Outcomes: ASAS-PR and ASDAS-ID.

Results: After screening 557 references (after de-duplication), 7 RCTs fulfilled the inclusion criteria, all concerning tumour necrosis factor inhibitors (TNFi) bDMARDs – table 1. ASAS-PR was the most commonly used remission-like definition- in 6 of the 7 trials, 1 of those as a composed measure with a magnetic resonance score. Despite different baseline populations (including r-axSpA and nr-axSpA), all these trials provide evidence of TNFi efficacy in achieving remission. The proportion of patients achieving ASAS-PR and ASDAS-ID varied between 33%–61.9% and 27.3%–55%, respectively, with a minimum and maximum follow-up periods of 28 to 254 weeks for ASAS-PR and 24 weeks to 5 years for ASDAS-ID.

Abstract SAT0269 – Table 1. bDMARD trials addressing ASAS-PR or ASDAS-ID as primary outcomes

Reference	Phenotype	Study design and duration	Drug (number of patients enrolled)	Primary Outcome	Results
Braun, 2008	r-axSpA	Extension 254 weeks	IFX/IFX vs PBO/IFX (38)	ASAS-PR	34.2% of patients achieved ASAS-PR
Sieper, 2012	r-axSpA and nr-axSpA	RCT 28 weeks	NPX + PBO (51) vs NPX + IFX (105)	ASAS-PR	ASAS-PR in 61.9% NPX+IFX vs 35.3% NPX+PBO (p<0.05)
Sieper, 2013	r-axSpA and nr-axSpA	Extension 52 weeks	NPX (40) vs no treatment (40) after partial remission under IFX+NPX or NPX+PBO	ASAS-PR	No statistically significant differences between the groups
Davis, 2008	r-axSpA	Extension 192 weeks	ETN/ETN (128) vs PBO/ETN (129)	ASAS-PR	44% of patients achieved ASAS-PR
Song, 2012	nr-axSpA	RCT (first part) 48 weeks	ETN (40) vs SSZ (36)	ASAS-PR plus MRI remission	ASAS-PR+MRI remission in 33% ETN vs 11% SSZ (p<0.05)
Sieper, 2011	r-axSpA	RCT and Extension 5 years	ADA/JADA vs PBO/JADA (311)	ASAS-PR and ASDAS-ID	ASAS-PR in 45% ASDAS-ID in 55%
van Heijde, 2014	r-axSpA	RCT (first part) 24 weeks	GOL (278) vs PBO (78)	ASDAS-ID	ASDAS-ID in 27.3% GOL vs 2.8% PBO (p<0.001)

Legend: ADA: adalimumab; ASAS-PR: ASAS- Partial Remission; ASDAS-ID: ASDAS Inactive Disease; ETN: etanercept; GOL: golimumab; IFX: infliximab; MRI: magnetic resonance image; NPX: naproxen; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; r-axSpA: radiographic spondyloarthritis; RCT: randomised controlled trial; SSZ: sulfasalazine, vs – versus.

Conclusions: Clinical trials addressing remission-like concepts as primary outcomes are scarce. ASAS-PR score was the most commonly used remission outcome. Depending on the studies, between one third to one half of patients treated with TNFi achieved ASAS-PR or ASDAS-ID. Considering nowadays aimed treatment targets, these data raise the unmet need for improved treatment options and strategies, that favour optimised remissions rates in axSpA patients.

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