survival for bDMARD naïve vs. non-naïve patients was similar for all diagnoses (RA, p=0.15; PsA, p=0.23; axSpA p=0.71), with trend towards better drug survival in bDMARD naïve RA and PsA patients (figure). 4 year drug survival in bDMARD naïve/non-naïve patients were: RA, 54/48%; PsA, 47/43%; axSpA, 48/46%, respectively. Subgroup analyses of patients with and without concomitant sDMARDs showed similar findings. A trend was seen towards better 3 month responses in bDMARD naïve vs. non-naïve patients, with statistically significant better responses for DAS28 in PsA and BASDAI and ASDAS in axSpA (table 1).

Conclusions: Golimumab drug survival was similar in bDMARD naïve vs. non-naïve RA, PsA and axSpA patients. A trend was seen towards better responses for bDMARD naïve patients. Identified predictors for golimumab drug discontinuation was female gender and no concomitant sDMARDs in PsA and female gender in axSpA.

Disclosure of Interest: B. Michelsen Consultant for: Novartis, J. Sexton: None declared, T. Kvien Grant/research support from: AbbVie, BMS, MSD, Pfizer, Roche and UCB, Consultant for: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celgene, Celsion, E Lilly, Epirus, Hospira, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz and UCB

DOI: 10.1136/annrheumdis-2018-eular.1885

SAT0266

THE RESPONSE TO TNF-BLOCKERS TREATMENT OF SPA PATIENTS IS INFLUENCED BY THE INTERPLAY BETWEEN HLA-B27 AND GUT MICROBIOTA COMPOSITION AT BASELINE.

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Background: The response to TNF-blockers in axial spondyloarthritis (AxSpA) is at least partially influenced by HLA-B27 through a still poorly understood mechanism.

Objectives: Given that HLA-B27 regulates the gut microbiota composition in rats2,3, we seek to evaluate the predictive value of the gut microbiota composition in AxSpA patients on their responsiveness to TNF-blockers.

Methods: A total of 58 patients was monocentrically recruited between October 2014 and May 2015. At baseline, these patients had an active disease despite NSAIDs intake and were eligible for treatment with a TNF-blocker, while having no history of inflammatory bowel disease (IBD). The mean BASDAI (±SD) was 45.2 (±21.4; ASDAS 2.8±0.9 and CRP 9.7±11.4 mg/l. Among these patients, 56 fulfilled the ASAS classification criteria (imaging arm) with sacro-ilitis on X-rays (n=37) or objective signs of inflammation on MRI (n=48). Two patients fulfilled the clinical arm. These patients were not subjected to antibiotics within 3 months before stool sample collection. Bacterial 16S rRNA gene sequencing of the V3-V4 region was performed on stools samples before and 3 months after TNF-blocker treatment. Beta diversity metrics were calculated on the abundance of operational taxonomic units (OTU) after their taxonomic assignment on quality-filtered sequences.

Results: Principal component analysis (PCA) ordination of Bray-Curtis similarity revealed that current smoking (compared with never or ever smokers) and HLA-B27 genotype were significantly associated with the overall composition of the microbiota at baseline. Moreover, the abundance of eleven bacterial OTUs was influenced by HLA-B27 genotype at baseline but not after 3 month of treatment. In contrast, we identified a bacterial signature that was linked to the smoking behaviour independently of TNF-blocker treatment, whereas the BASDAI and ASDAS indices were significantly associated to the general composition of the gut microbiota after the 3 month treatment. In line with a previous report3, the abundance of Ruminococcus granus was not associated with disease activity in the absence of IBD. Interestingly, the abundance of 5 and 7 bacterial OTUs at baseline was associated with the response to TNF-blockers assessed by BASDAI and ASDAS, respectively. Among these candidates, the abundance of one bacterial OTU belonging to the Clostridiales order was associated with a better response to the treatment and with the HLA-B27 genotype.

Conclusions: Anti-TNF treatment was found to modulate the HLA-B27-induced variations of the intestinal microbiota of AxSpA patients. Moreover, the abundance of a subset of OTUs at baseline was found to predict the responsiveness to TNF-blockers. Further functional studies will be conducted to assess how these taxa can be use as predictors of the treatment outcome.

REFERENCES:

Disclosure of Interest: None declared


SAT0266

USE OF CONVENTIONAL SYNTHETIC DMARDS AND BIOLOGICAL DMARDS IN PATIENTS WITH ENTEROPATHIC SPONDYLOARTHRITIS: A COMBINED GASTRO-RHEUMATOLOGICAL APPROACH

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Background: Enteropathic spondyloarthritides (eSpA) is a chronic autoimmune disease associated with inflammatory bowel disease (IBD) that is poorly diagnosed and managed.

Objectives: To assess the diagnostic and therapeutic effect of a combined gastro-rheumatological approach in eSpA patients.

Methods: IBD-patients with joint pain referred to a dedicated rheumatologist by gastroenterologist were enrolled. Clinical and biochemical variables, SpA and intestinal disease activity measures, and treatment (biologic; bDMARDs and conventional synthetic; csDMARDs) were recorded at baseline, 3, 6, 12 and 24 months. The association between treatment on demographic and clinical characteristics was evaluated by logistic regression.

Results: From a total of 229 IBD patients, 147 (64.2%) were diagnosed with eSpA, 96 (65.3%) showing peripheral involvement and 51 (34.7%) with axial involvement. The majority (67.3%) of eSpA patients were female (n=99), median age and disease duration of 46 and 14.6 years. bDMARD treatment increased over the follow-up period (baseline-24 months: 32.6%>60%; AOR:3.45, 95% CI: 1.93–6.2, p<0.001), however, their use was less frequent in elderly patients (AOR: 0.73, 95% CI: 0.56–0.96, p=0.023), in ulcerative colitis patients (AOR:0.43, 95% CI:0.2–0.94, p=0.024) and in patients with peripheral involvement (AOR:0.53, 95% CI:0.3–1.04, p=0.067). csDMARD use was increased in patients with peripheral involvement (AOR: 4.65, 95% CI:12.09–10.33, p<0.001) and in patient with ulcerative colitis (AOR:2.30, 95% CI:1.13–4.67, p=0.021) (figure 1). CRP, ESR, ASDAS-ESR levels and BASFI were significantly decreased over the follow-up period whereas pMayo score, BASDAI and HAQ-S were unchanged (figure 2).

Disclosure of Interest: None declared


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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

Abstract 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, SFI36 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 shown previously1. Here we present 54 week safety and efficacy data in ITT population from international double-blind randomised ASART-2 clinical trial. No statistically significant differences in rates of AEs were found between study groups.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>BCD-055, n (%)</th>
<th>Infliximab, n (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE/SAE</td>
<td>82 (62.12)</td>
<td>43 (64.18)</td>
<td>0.896</td>
</tr>
<tr>
<td>Any SAE</td>
<td>7 (5.30)</td>
<td>5 (7.46)</td>
<td>0.376</td>
</tr>
<tr>
<td>Therapy-related AE/SAE</td>
<td>40 (30.30)</td>
<td>26 (38.81)</td>
<td>0.296</td>
</tr>
<tr>
<td>Therapy-related SAE</td>
<td>5 (3.79)</td>
<td>4 (5.97)</td>
<td>0.489</td>
</tr>
<tr>
<td>Any SAE/SAE grade 3–5</td>
<td>18 (13.64)</td>
<td>11 (16.42)</td>
<td>0.754</td>
</tr>
<tr>
<td>Therapy-related AE grade 3–5</td>
<td>11 (8.33)</td>
<td>7 (10.45)</td>
<td>0.818</td>
</tr>
<tr>
<td>Treatment withdrawal due to SAE/SAE</td>
<td>11 (8.33)</td>
<td>7 (10.45)</td>
<td>0.818</td>
</tr>
<tr>
<td>Deaths</td>
<td>1 (0.76)</td>
<td>0 (0.00)</td>
<td>1.000</td>
</tr>
<tr>
<td>ADA positive</td>
<td>27 (21.26)</td>
<td>13 (20.63)</td>
<td>0.920</td>
</tr>
<tr>
<td>ADA positive, confirmed by neutralisation assay</td>
<td>4 (3.15)</td>
<td>4 (6.35)</td>
<td>0.443</td>
</tr>
</tbody>
</table>

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.

REFERENCE:


Abstract 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.

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 score. Most common reported AEs were infections, hematologic and vascular disorders, hypersensitivity reactions. Formation of ADA to secukinumab was detected with similar frequency in both groups.

Conclusions: The 54 week results confirms previous 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.

REFERENCE:


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

Abstract SAT0268 – Figure 1. Improvement in ASAS20 at w208 was numerically lower with secukinumab 150 mg over 208 wks (figure 1).