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POS0233 THE EFFICIENCY OF TREATMENT OF COXITIS IN AXIAL SPONDYLOARTHRITIS: EXPERIENCE OF REAL CLINICAL PRACTICE

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Background: Standard therapy for axial spondyloarthritis (axSpA) is effective in inflammatory lesions of the axial skeleton and peripheral arthritis, but its effect on coxitis has not been studied.

Objectives: To assess the effectiveness of anti-TNF therapy for coxitis in patients with axSpA.

Methods: An open observational study was conducted. There were 56 patients with axSpA and coxitis for 2 years who received NSAIDs or NSAIDs+anti-TNF therapy in real clinical practice. The study included only those patients who completed a 2-year follow-up period. All patients regardless of complaints underwent X-ray examination of the pelvis, ultrasound and magnetic resonance imaging (MRI) of the hip joints. An increase in the cervical-capsular distance (CCD) of more than 7 mm and the presence of asymmetry between the joints of more than 1.5 mm were taken for coxitis on ultrasound of the hip joint. The presence of synovitis and/or osteitis was taken for coxitis on MRI. The average age was 31.1±7.0 years, with an average duration of the disease 74.5±100.1 months. HLA-B27 positive were 52 (92%) patients.

Results: A comparative analysis of clinical, laboratory and other parameters of the disease was carried out against the background of 2-year follow-up of patients who were constantly taking only NSAIDs or their combination with anti-TNF therapies (Table 1).

Table 1.

Parameters	Group NSAIDs+ anti-TNF n=27 baseline	Group NSAIDs+ anti-TNF n=27 after 2 y	p	Group NSAIDs n=29 baseline	Group NSAIDs n=29 after 2 y	p
BASRI hip ≥2; n %	10 (37%)	18 (67%)	>0,05	6 (21%)	14 (48%)	<0,05
MRI coxitis; n %	27 (100%)	19 (70%)	<0,05	28 (97%)	24 (83%)	>0,05
CCDmm; Me, [25 %; 75%]	7,9 [7,0;8,2]	7,2 [6,1;8,3]	<0,05	7,2 [6,2;7,8]	6,2[5,6;7,8]	>0,05
CRP,mg/L; Me, [25 %; 75%]	23,7[8,4;56]	6,0 [1,0;17,3]	<0,05	10,3 [2,9;18,6]	8,4[2,9;18,5]	>0,05
ESR; Me, [25 %; 75%]	25 [15;38]	15,0 [5;35,2]	<0,05	13 [7,8;25,5]	13 [6;26,3]	>0,05
ASDAS CRP; Me, [25 %; 75%]	3,5 [2,4;4,7]	2,0 [1,0;2,4]	<0,05	2,6 [1,3;3,6]	2,0[1,1;2,3]	>0,05
BASDAI; Me, [25%; 75%]	4,7[4,2;6,9]	2,2 [2,0;3,7]	<0,05	4,2 [2,4;5,8]	2,2[1,4;4,2]	>0,05
BASFI; Me,[25%;75%]	4,0 [2,0;6,5]	1,9 [0,9;2,9]	<0,05	1,2 [0,3;2,5]	0,9[0,4;2,8]	>0,05

Conclusion:

1. Anti-TNF+NSAIDs therapy with 2 years of use effectively controls the activity of axSpA.

2. Two-year therapy with NSAIDs in combination with anti-TNF, reduces the inflammation of hip joints in some patients according to ultrasound and MRI data.

3. The present study did not conclusively confirm that 2-year anti-TNF therapy with NSAIDs effectively prevents the progression of X-ray bursitis in axSpA.

4. Further studies are needed to improve the effectiveness of treatment of coxitis in axSpA.

Disclosure of Interests: None declared.

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POS0234 SECUKINUMAB RETENTION AND SAFETY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS OR ANKYLOSING SPONDYLITIS: 2 YEAR INTERIM RESULTS OF THE OBSERVATIONAL SERENA STUDY

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Background: SERENA is an ongoing, prospective, non-interventional study evaluating retention, effectiveness, safety/tolerability and quality of life in more than 2900 patients (pts) with moderate to severe plaque psoriasis, active psoriatic arthritis (PsA) or active ankylosing spondylitis (AS) treated with secukinumab (SEC) at 438 sites across Europe for a period of up to 5 years¹.

Objectives: We present interim results reporting SEC treatment retention and safety data through 2 years in the PsA and AS pts enrolled in the study.

Methods: This interim analysis presents data from 534 PsA and 470 AS pts who were enrolled (target population fulfilling all eligibility criteria) in the study and were followed up for at least 2 years. Pts (aged ≥18 years) with active PsA or AS should have received at least 16 weeks SEC treatment before enrolment in the study¹. Retention rate was defined as the percentage of pts who have not discontinued SEC treatment. A treatment break was defined as interruption of therapy for at least 3 months after last injection.

Results: The mean treatment duration prior to enrolment in the study was 1.0 year and 0.91 year for PsA and AS, respectively. The retention rates for SEC after 1 year since enrolment and since initiation of treatment were: PsA, 85.2% [n=519, CI: 82.01–88.32] and 96.8% [n=528, CI: 95.18–98.38]; AS, 85.8% [n=452, CI: 82.52–89.17] and 94.2% [n=464, CI: 91.94–96.42], respectively. After 2 years since enrolment and since initiation of treatment, the retention rates were: PsA, 74.9% [n=498, CI: 70.99–78.81] and 87.0% [n=515, CI: 83.99–89.99]; AS, 78.9% [n=437, CI: 75.01–82.88] and 84.8% [n=454, CI: 81.39–88.21], respectively. Survival probabilities for individual indications are presented in Figure 1. At baseline, the majority of PsA (79.5%; n/N=423/532) pts were receiving SEC 300 mg, while 97.0% (n/N=456/470) of AS pts were receiving SEC 150 mg. The majority of pts continued their initial SEC dose; "no dose change" in SEC treatment was reported after 1 and 2 years in the study (Year 1: PsA, 93.4% [n=499] and AS, 92.6% [n=435]; Year 2: PsA, 89.7% [n=479] and AS, 87.9% [n=413]). SEC treatment break was recorded for 31 PsA pts [median (min, max) treatment break duration in days: 125.0 (61, 461)] and for 42 AS [118.0 (61, 813)] pts mainly due to adverse events reported in 58.1% (n=18) and 45.2% (n=19) of pts, respectively. The retreatment started with monthly dosing in most of the cases: PsA, 80.6% (n/N=25/31) and AS, 76.2% (n/N=32/42). No new or unexpected safety signals were reported (Table 1).

Conclusion: Secukinumab retention rates in a real world setting after more than 2 years since initiation of treatment and after 2 years since enrolment in the study indicate high persistence rates. Safety data collected prospectively for up to 2 years confirm the favorable safety profile of secukinumab.

Figure: Time to treatment discontinuation of secukinumab by individual indications

REFERENCES:

[1] Kiltz, U et al. Adv Ther 2020; 37:2865–83.

Table 1. Safety profile of treatment-emergent adverse events within the study period

AE summary, n (%)	PsA		AS	
	N=575	N=499	N=575	N=499
Subject with any AE	239 (41.6)	289 (50.3)	203 (40.7)	247 (49.5)
Subject with any serious AE	29 (5.0)	45 (7.8)	29 (5.8)	44 (8.8)
Subject with AE leading to discontinuation	55 (9.6)	84 (14.6)	47 (9.4)	62 (12.4)
Death	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
AEs of special interest, n (IR per 100 subject-years)				
Serious infections and infestations	5 (0.96)	9 (0.95)	8 (1.78)	11 (1.33)
<i>Candida</i> infections	1 (0.19)	2 (0.21)	2 (0.44)	2 (0.24)
Malignancy	5 (0.96)	7 (0.74)	N/R	3 (0.36)
Major adverse cardiovascular events	N/R	1 (0.11)	2 (0.44)	3 (0.36)
Inflammatory bowel disease	N/R	N/R	1 (0.22)	1 (0.12)

N, total number of patients in the safety set; n, number of patients with event; AE, adverse events; IR, incidence rate; N/R, not reported.

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POS0235

COMPARISON OF AXIAL AND PERIPHERAL MANIFESTATIONS IN PATIENTS WITH PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS IN UPADACITINIB CLINICAL TRIALS

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Background: Axial, peripheral, and other disease manifestations often overlap between psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Upadacitinib (UPA) is an oral Janus kinase inhibitor under evaluation for the treatment of PsA and AS.

Objectives: To describe and compare baseline characteristics and UPA efficacy across 4 subgroups of patients (pts) from clinical trials: active PsA (with/without axial involvement) and active AS (with/without peripheral involvement).

Methods: Baseline characteristics and efficacy of UPA in reducing axial and peripheral signs and symptoms were assessed via an integrated analysis across the 4 pt subgroups from the SELECT-PsA 1, ¹ SELECT-PsA 2, ² and SELECT-AXIS³ studies. Analyses of baseline characteristics included pts in the UPA 15mg once daily (QD), UPA 30mg QD, and placebo (PBO) groups; efficacy analyses included pts in the UPA 15mg QD group only. Axial involvement in PsA (axial PsA) was determined by investigator assessment. Peripheral involvement in AS was defined based on presence of tender or swollen joints (TJC68 >0 or SJC66 >0), or presence of enthesitis at baseline (Maastricht Ankylosing Spondylitis Enthesitis Score >0).

Results: 2102 pts (UPA 15mg; UPA 30mg; PBO) were evaluated across the 4 subgroups (PsA [with/without axial involvement]: 626/1289; AS [with/without

peripheral involvement]: 135/52). 33% of pts with PsA had axial PsA; 72% of pts with AS had peripheral symptoms. Pts with axial PsA had higher peripheral joint (TJC68 and SJC66) and skin (psoriasis) burden than pts with AS with peripheral involvement ($p<0.0001$). Pts with AS with peripheral involvement had significantly greater overall pain (pt's assessment of pain; $p=0.0002$) and back pain (BASDAI Q2; $p<0.0001$) scores, and higher total BASDAI ($p=0.0076$) and ASDAS ($p=0.0351$) scores than pts with axial PsA; physician's global assessment of disease activity, and peripheral pain and tenderness (BASDAI Q3 and Q4) were numerically similar for these 2 subgroups (Table 1). The efficacy of UPA 15mg (measured using ASDAS and BASDAI) was generally consistent across the 4 pt subgroups regardless of peripheral or axial involvement (Figure 1).

Conclusion: Pts with PsA with axial involvement and pts with active AS showed some differences in baseline characteristics but similar improvements versus placebo with UPA 15mg QD.

REFERENCES:

- [1] McInnes I, et al. Ann Rheum Dis 2020;79(Suppl 1):16–17; 2. Genovese MC, et al. Ann Rheum Dis 2020;79(Suppl 1):139; 3. van der Heijde D, et al. Lancet 2019;394:2108–17.

Table 1. Baseline demographics, medical history, and disease characteristics

	PsA with axial involvement n=626	PsA without axial involvement n=1289	AS with peripheral involvement n=135	AS without peripheral involvement n=52	p-value (PsA with axial involvement versus AS with peripheral involvement)
Mean (SD), unless otherwise specified					
Male, n (%)	300 (47.9)	583 (45.2)	88 (65.2)	44 (84.6)	0.0003
Age, years	50.7 (12.6)	52.0 (12.0)	46.6 (12.7)	42.2 (11.4)	0.0008
Body mass index, kg/m ²	30.3 (7.1)	30.7 (6.8) ^a	26.7 (4.9)	26.8 (5.2)	*
Duration of disease symptoms, years	11.2 (9.3) ^b	10.4 (9.5) ^a	14.6 (10.9)	14.0 (10.6)	0.0009
Duration of disease since diagnosis, years	7.7 (8.0)	7.3 (8.0)	7.0 (9.2)	6.8 (8.4)	0.3738
TJC68	23.6 (16.4)	20.6 (14.6)	5.3 (8.2)	0	*
SJC66	11.9 (9.0)	11.2 (8.2)	1.5 (3.2)	0	*
Psoriasis, n (%)	616 (98.4)	1269 (98.4)	7 (5.2)	0	*
Uveitis, n (%)	1 (0.2)	5 (0.4)	3 (2.2)	1 (1.9)	0.0191
Inflammatory bowel disease, n (%)	10 (1.6)	13 (1.0)	2 (1.5)	2 (3.8)	1.0000
PhGA	6.7 (1.7)	6.5 (1.7)	6.7 (1.5) ^c	6.9 (1.7) ^b	0.6960
Pain, VAS 0–10	6.3 (2.0) ^b	6.1 (2.2) ^d	6.9 (1.6) ^a	6.8 (1.7) ^a	0.0002
ASDAS (CRP)	3.4 (1.0) ^e	3.1 (1.0) ^f	3.5 (0.7) ^a	3.7 (0.8) ^a	0.0351
BASDAI (Total score)	6.0 (2.1) ^g	5.5 (2.2) ^f	6.4 (1.6)	6.3 (1.8) ^a	0.0076
BASDAI Q2 (Back pain)	6.1 (2.7) ^g	4.8 (3.2) ^f	7.2 (1.7)	7.2 (1.6) ^a	*
BASDAI Q3 (Peripheral pain/swelling)	6.3 (2.4) ^g	6.0 (2.6) ^f	5.9 (2.4)	5.5 (2.4) ^a	0.0747
BASDAI Q4 (Tenderness)	5.8 (2.6) ^g	5.6 (2.7) ^f	6.1 (2.5)	5.7 (2.4) ^a	0.3196

* $p<0.0001$ Data missing for ^an=1, ^bn=3, ^cn=6, ^dn=11, ^en=4, ^fn=14

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