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AB0761 SECUKINUMAB FOR THE TREATMENT OF PSORIATIC ARTHRITIS IN REAL LIFE: AN ITALIAN EXPERIENCE

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Background: Secukinumab is a novel treatment for psoriatic arthritis (PsA) but data from real life are still missing.

Objectives: The aim of this study is to evaluate a wide cohort of PsA patients on secukinumab followed in 7 Italian rheumatologic centers.

Methods: Two-hundred and seventy-nine patients affected by PsA and on secukinumab were enrolled. Data on disease characteristics, previous and ongoing treatments, comorbidities and duration of follow-up were collected. In particular DAPSA and ASDAS were used to assess articular and axial disease activity.

Results: Mean age of our cohort was 53±11 years and BMI 26.4±5.1 kg/m² with the majority of patients being female (63.8%). Mean disease duration was 9.7±7.5 years and mean follow-up was 10.9±6.8 years. For 100 patients (35.8%) secukinumab was their first line biologic treatment and 41 (50.5%) were in monotherapy. DAPSA was 25.9±10.5 at baseline, 15.9±9.7 at M3, 12.9±8.4 at M6, 9.8±7.1 at M12 with a significant downward decrease at every visit as compared to baseline ($p<0.001$ for each comparison to baseline). ASDAS at baseline was 3.27±1.15, 2.32±0.99 at M3, 2.04±1.12 at M6, 1.96±0.88 at M12 with a significant downward decrease at M3 and M6 ($p<0.001$) and a downward trend for M12 ($p=0.064$), probably because of the small number of patients with axial involvement at M12 (15). After 12 months of treatment 70.6% with axial involvement and 76.6% with articular manifestations had an inactive disease/low disease activity, accordingly to ASDAS and DAPSA respectively. Forty patients (14.3%) stopped the treatment during the follow up mainly because of primary or secondary loss of efficacy (18 and 10, respectively). Only 9 patients suspended the treatment because of adverse events, of which 5 because of reactions at site of injection.

The retention rate at 12 months was very good in the whole population (figure), and in particular in patients with entesitis at the baseline (10.5 vs. 11.2, $p=0.038$). No differences in survival were found when dividing patients accordingly to BMI, although overweight or obese patients showed a trend for a better retention rate (10.6 vs 10.9, $p=0.089$). Interestingly no differences were found between naïve and non-naïve patients ($p=0.895$) and between those in monotherapy or in combination therapy ($p=0.925$).

Conclusion: This is one of the first real life studies on secukinumab and shows a very good efficacy and safety of this treatment in PsA patients, also for the articular manifestations, as shown by a significant decrease of DAPSA over a 12-months follow up.

Figure. Twelve-months retention rate of patients on Secukinumab

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AB0762 TREATMENT WITH TOFACITINIB IN REFRACTORY PSORIATIC ARTHRITIS. MULTICENTER STUDY OF CLINICAL PRACTICE

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Background: Tofacitinib (TOFA) is the first inhibitor of JAK kinases with approval for the treatment of psoriatic arthritis (PsA) in Europe (July 2018)¹. TOFA has shown efficacy in refractory patients to anti-TNF².

Objectives: **A)** to assess efficacy and safety of TOFA in the first cases in Spain in clinical practice. **B)** to compare the profile of clinical practice patients with clinical trial.

Methods: Study of 41 patients of clinical practice with PsA treated with TOFA in Spain. The diagnosis of PsA was made using CASPAR criteria. Patients who received at least one dose of TOFA were included. Results are expressed as percentage, mean±SD or median [IQR].

Results: 41 patients (23 ♀/18 ♂), mean age of 50.2±10.7 years (table 1). Pattern joint involvement was as follows: peripheral (n=25), axial (1) and mixed (15). During the PsA evolution, in addition to arthritis, patients also presented entesitis (60.9%), nail involvement (39%) and dactylitis (31.7%).

Table 1.

	CLINICAL TRIAL Gladman D, et al. (N=131)	CLINICAL PRACTICE (N=41)
Baseline demographic parameters		
Age, years (mean±SD)	49.5±12.3	50.2±10.7
Sex, n (%)	67M/64F (51/49)	18M/23F (46.6/53.4)
Disease Characteristics		
Duration of psoriatic arthritis, year (mean±SD)	9.6±7.6	12.6±9.1
HAQ-DI	1.3±0.7	1.9±0.4 (n=22)
Swollen joint count, mean±SD	12.1±10.6	5.7±5.3
Painful joint count, mean±SD	20.5±13.0	8.7±6.1
Elevated CRP, n (%)	85 (65)	33 (80.5)
PASI score, median [IQR]	7.6 [0.6–32.2]	6 [0–15]
Day 1 oral glucocorticoid use, n (%)	37 (28)	25 (60.9)
Concomitant synthetic DMARD, n (%)		
- Methotrexate	98 (75)	25 (60.9)
- Leflunomide	12 (9)	8 (19.5)
- Sulfasalazine	21 (16)	0 (0)
- Others	2 (2)	0 (0)
TL of previous Anti-TNF inhibitors, mean±SD	1.7±1.0	2.5±1.4
TL of previous other biological no anti-TNF, n (%)	11 (8)	52 (126.8)
Adverse event, n (%)	72 (55)	10 (24.4)
Discontinuation due to adverse event, n (%)	2 (2)	1 (2.4)

Table 2.

	Baseline (N=41)	1st month (N=41)	6th month (N=13)
Prednisone, n (%)	25 (60.9%)	8 (43.9%)	6 (46%)
Dose (mean±SD)	9.4±6.1	7.6±4.7	5.6±2.9
Methotrexate, n (%)	9 (21.9%)	6 (14.6%)	3 (23%)
Dose (mean±SE)	18.8±5.8	19.5±3.3	21.6±2.8
N. Patients: Skin involvement, n (%)	22 (53.6%)	8 (19.5%)	2 (15.4%)
N. Patients: Nail involvement, n (%)	12 (29.2%)	7 (17.1%)	6 (46.2%)
N. Patients: arthritis, n (%)	38 (92.6%)	8 (19.5%)	2 (15.4%)
- Swollen joint count, median [IQR]	4 [2–7]	2 [1–4.3]	0 [0–1.5]
- Painful joint count, median [IQR]	7 [4.3–11.5]	2 [1–5]	1 [0–2]
N. Patients: enthesitis, n (%)	11 (26.8)	8 (19.5)	1 (7.7%)
N. Patients: dactylitis, n (%)	7 (17.1)	4 (9.7)	ND
CRP mg/dl, median [IQR]	2.36 [0.95–7.5]	1.7 [0.5–4.5]	0.98 [0.4–5]
DAS28, median [IQR]	5.1 [4.7–5.7]	3.8 [3.2–4.6]	2.9 [2.4–3.3]
DAPSA, median [IQR]	28.3 [23.2–32.3]	14 [7.2–31.1]	7.6 [4.8–19.2]
PASI, median [IQR]	6 [0–15]	5 [0.7–9.5]	2 [0–8]

Prior TOFA, most patients had received oral prednisone or equivalent (max. 17.9±13.6 mg/d), synthetic immunosuppressants (mean 1.9±0.7) and biological therapy (TB) (3.4±1.9). TB were as follows: etanercept (29), adalimumab (29), infliximab (16), golimumab (13), certolizumab (14), secukinumab (30), ustekinumab (22). Apremilast was used in 10.

After a mean follow-up of 12.6±9.1 years after the PsA diagnosis, TOFA was started (5 mg/12 h). 60.9% associated prednisone (9.4±6.1 mg/d). In 17 (41.5%) TOFA was started in combined therapy: methotrexate (9) and leflunomide (8); in the remaining 24, monotherapy was prescribed. In addition to active arthritis patients presented skin involvement (53.6%), enthesitis (26.8%), nail involvement (29.2%) and dactylitis (17.1%).

Patients of clinical practice compared with clinical trial have a longer duration of PsA, functional disability (HAQ) and received a higher proportion of corticosteroids and TB (anti-TNF and non-anti-TNF) (table 1).

After a median follow-up of 4 [3–10.5] months, patients showed prompt improvement in the main variables, both in activity indexes (PASI, DAS28, DAPSA) and laboratory test (table 2). Minor side effects were reported in 10 patients (gastrointestinal symptoms), and TOFA was discontinued in 1 due to persistent symptoms.

Conclusion: In this preliminary study, first patients of clinical practice in Spain with TOFA in PsA had a longer evolution and received a greater number of TB than those of clinical trial. As in the TOFA clinical trial, it seems effective, rapid and relatively safe in daily clinical practice for refractory PsA.

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AB0763 SAFETY OF ABATACEPT TREATMENT OVER 2 YEARS IN A PHASE III ACTIVE PSORIATIC ARTHRITIS RANDOMIZED TRIAL (ASTRAEA)

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Background: In the placebo (PBO)-controlled Phase III ASTRAEA study (ClinicalTrials.gov, NCT01860976) in psoriatic arthritis (PsA), abatacept (ABA) 125 mg SC weekly significantly increased the ACR20 response rate at Week 24 versus PBO (39.4% vs 22.3%, respectively; p<0.001; primary endpoint).¹ Numerical benefits in physical function, enthesitis and dactylitis and a modest impact on psoriasis lesions were also seen at Week 24. Efficacy was maintained or improved up to Week 52.¹

Objectives: To assess ABA safety up to 2 years in patients (pts) enrolled in ASTRAEA.

Methods: Pts with active PsA were randomised 1:1 to ABA or PBO for 24 weeks followed by 28 weeks' open-label (OL) ABA (total time on study: 52 weeks); pts without ≥20% improvement in joint counts at Week 16 (early escape) were switched to OL ABA (total time on study: 44 weeks).¹ Pts could subsequently receive OL ABA in a 52-week long-term extension (LTE; Year 2) for the collection of safety data. The proportions of pts in the cumulative ABA population (all pts who received ≥1 dose of ABA at any time in the study) with AEs (all AEs, serious AEs [SAEs], deaths, AEs leading to discontinuation), laboratory marked abnormalities and anti-ABA antibodies over the cumulative ABA period (date of first treatment dose to end of LTE) were recorded in 1-year and 6-month intervals.

Table 1. Summary of safety up to Year 1 and Year 2 (cumulative ABA period; cumulative ABA population)

	From baseline up to Year 1 (N=398)		From baseline up to Year 2 (N=398)	
	n (%)	Incidence rate per 100 patient-years	n (%)	Incidence rate per 100 patient-years
Deaths	0	0	0	0
SAEs	34 (8.5)	12.1	50 (12.6)	8.9
Treatment-related ¹ SAEs	5 (1.3)	NA	10 (2.5)	NA
Discontinued due to SAEs	8 (2.0)	NA	8 (2.0)	NA
AEs	273 (68.6)	184.9	322 (80.9)	151.2
Treatment-related AEs	81 (20.4)	NA	104 (26.1)	NA
Discontinued due to AEs	13 (3.3)	NA	18 (4.5)	NA
AEs reported in ≥5% of patients				
Nasopharyngitis	25 (6.3)	9.0	44 (11.1)	7.7
Upper respiratory tract infection	28 (7.0)	10.2	40 (10.1)	7.0
Bronchitis	26 (6.5)	9.4	38 (9.5)	6.6
Urinary tract infection	18 (4.5)	6.4	29 (7.3)	5.0
Influenza	–	–	29 (7.3)	4.9
Back pain	–	–	23 (5.8)	3.9
Diarrhoea	–	–	22 (5.5)	3.7
Sinusitis	–	–	21 (5.3)	3.5
AEs of special interest				
Infections ²	162 (40.7)	75.9	226 (56.8)	62.7
Malignancies ³	4 (1.0)	1.4	4 (1.0)	0.7
Autoimmune events ⁴	1 (0.3)	0.4	4 (1.0)	0.7
Local injection-site reactions ⁵	5 (1.3)	1.8	6 (1.5)	1.0
AEs within 24 hours ⁶	94 (23.6)	38.7	141 (35.4)	34.0

¹Causal relationship between study drug and an AE was determined by an investigator physician

²SAEs of infection reported during the LTE included osteomyelitis, intervertebral discitis and cellulitis. Three pts discontinued during the LTE due to the following infections: hepatitis A, Epstein-Barr virus infection and intervertebral discitis

³Bowen's disease, carcinoma in situ of skin, prostate cancer and transitional cell carcinoma. Only transitional cell carcinoma was treatment related. No malignancies were reported during the LTE

⁴Uveitis, hyperthyroidism, Sjögren's syndrome and celiac disease. No autoimmune events reported in the LTE were serious or led to discontinuation of ABA therapy

⁵No local injection-site reactions led to treatment discontinuation

⁶None were suggestive of systemic immune reactions

ABA=abatacept; LTE=long-term extension; NA=not available; pt=patient; SAE=serious AE