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EFFECTIVENESS AND SAFETY OF INFLIXIMAB AND GOLIMUMAB IN ANKYLOSING SPONDYLITIS PATIENTS FROM A PROSPECTIVE OBSERVATIONAL REGISTRY

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Background: Long-term registries are essential to evaluate new therapies in a patient population that differs from clinical trial and usually varies over time.

Objectives: To describe the profile of ankylosing spondylitis (AS) patients treated with infliximab (IFX) or golimumab (GLM) treatment in Canadian routine care along with its long-term effectiveness and safety.

Methods: 810 AS patients treated with IFX or GLM were enrolled into the Biologic Treatment Registry Across Canada (BioTRAC) registry between 2005-2015 and 2010-2017, respectively. Study visits occurred at baseline and every 6 months thereafter, as needed per routine care. Effectiveness was assessed with changes in ASDAS, BASDAI, BASFI, MDGA, HAQ-DI, PtGA, back pain and acute phase reactants. Safety was evaluated with the incidence of adverse events (AEs) and drug survival rates.

Results: Of the 389 IFX- and 421 GLM-treated patients, the proportion of males were 62.7% and 59.1%, the mean age were 45.6 and 45.7 years and the mean disease duration were 8.6 and 6.0 years, respectively. Most patients were bio-naïve (>82.7%). Interestingly, we observed a significant decrease in disease duration in the IFX cohort from a median of 8.0 to 3.5 and 1.0 years in 2005-2008, 2009-2012 and 2013-2015, respectively ($p<0.001$). A reduction in baseline BASFI score (6.3 vs. 5.9 vs 5.1; $P=0.011$) and in the proportion of patient in ASDAS very high disease activity (48.4%, 43.8%, 30.3%; $p=0.004$) were also observed. As for the GLM cohort, most disease parameters including median disease duration (1.6 years), mean baseline BASFI (5.3) and the proportion of patients in ASDAS very high disease activity (48%) remained similar from 2010-2017.

Treatment with both IFX and GLM significantly improved all disease parameters over time ($P<0.001$) from baseline up to 120 and 84 months, respectively, with similar efficacy between agents.

AEs were reported for 67.9% and 70.5% (136 and 131 events/100 PYs) and SAEs for 15.4% and 8.1% (10.5 and 22.7 events/100 PYs) covering 1251.3 and 674.8 years of exposure for IFX- and GLM-treated patients, respectively. The most frequently occurring AEs (>7% of patient in either group) were upper respiratory tract infection, arthralgia and back pain. Two deaths occurred in IFX-treated patients (myocardial infarct, drowning) and two among GLM-treated patients (oropharyngeal cancer; neutropenia, staphylococcal/pseudomonas infections, septic shock).

The proportion of patients who discontinued treatment were 65.8% over a mean 3.2 years of exposure in the IFX cohort and 56.8% over 1.6 years in the GLM cohort.

Conclusion: Both IFX and GLM treatment significantly reduced disease activity and improved functionality in a similar fashion and were well tolerated in patients with AS. Differences in baseline characteristics over time demonstrate improvement in early diagnosis of AS and earlier access to biologic therapies.

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AQUILA STUDY IN GERMANY – REAL WORLD ADHERENCE AND PERSISTENCE OF SECUKINUMAB TREATMENT IN ANKYLOSING SPONDYLITIS AND PSORIATIC ARTHRITIS PATIENTS – AN INTERIM ANALYSIS

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Background: Secukinumab (SEC) has been shown to be an effective treatment for patients (pts) with ankylosing spondylitis (AS) and psoriatic arthritis (PsA) in several phase III studies^{1,2}. Clinical studies reduce confounding factors, but do not guarantee the same results in real world where treating physicians deal with comorbidities, adherence and persistence challenges. Especially medication adherence has a direct impact on health outcomes. However, there is limited information on the adherence and persistence of SEC in routine care.

Objectives: The aim of this interim analysis is to report baseline (BL) characteristics and to assess adherence rate as well as treatment persistence of SEC in AS and PsA pts under real world conditions.

Methods: AQUILA is an ongoing, non-interventional study enrolling 2000 pts with active AS or PsA in Germany. Adherence was calculated as the proportion of the accumulated actual dose divided by the accumulated target dose (according to summary of product characteristics) during the maintenance phase (week 6 to 52). Adherence rate was calculated as the proportion of pts who achieved an adherence of >80% at wk 52. These calculations included pts who discontinued treatment with SEC; still ongoing pts were excluded from this interim analysis. Treatment persistence (time from study inclusion, i.e. date of informed consent, until treatment discontinuation) stratified by biologic/biosimilar (Bx) pretreatment was analyzed using Kaplan-Meier plots.

Results: This interim analysis describes 952 pts (AS n=311, PsA n=641) who were included at BL. In total, 51.4% (n=489) of the pts were female and 48.6% (n=463) male, mean age was 50.8 years, and 67.8% (n=645) were pretreated with Bx. At treatment start with SEC, pts presented with a number of extra-articular manifestations/comorbidities: plaque psoriasis 11.6% (n=36) in AS and 66.3% (n=425) in PsA, uveitis 6.4% (n=20) in AS and 1.7% (n=11) in PsA, depression 15.4% (n=48) in AS and 15.4% (n=99) in PsA, coronary heart disease 3.5% (n=11) in AS and 7.9% (n=51) in PsA, stroke 0.6% (n=2) in AS and 1.9% (n=12) in PsA, and heart insufficiency 1.6% (n=5) in AS and 3.0% (n=19) in PsA.

Adherence rates for SEC [95% CI] at week 52 were 64.5% [58.3,70.5] and 56.0% [51.5; 60.4] for AS and PsA, respectively.

In both AS and PsA, more Bx-pretreated pts discontinued treatment than Bx-naïve pts (AS: 38.0% versus 18.9%; PsA: 32.3% versus 20.7%). The most frequent reason for discontinuation was "adverse event/insufficient response/loss of efficacy" in both Bx-pretreated (n=73, 33.0%/n=111, 26.2%) as well as in Bx-naïve (n=10, 11.1%/n=34, 15.7%) AS/PsA pts. Moreover, Kaplan-Meier analysis showed that in both AS (Figure 1a) and PsA (Figure 1b) groups, Bx-naïve pts who received SEC as first line therapy had a higher persistence rate than those pretreated with Bx.