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DOES SMOKING AFFECT SECUCINUMAB TREATMENT OUTCOMES AND SAFETY IN PATIENTS WITH ANKYLosing SPONDYLITIS? – REAL WORLD DATA FROM THE GERMAN AQUILA STUDY

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Background: There is growing body of evidence that smoking is associated with more active and severe disease in patients (pts) with ankylosing spondylitis (AS).1,2 The German non-interventional study AQUILA provides real-world data on the influence of smoking on therapeutic effectiveness and safety under secucinumab (SEC), a fully human monoclonal antibody that selectively inhibits interleukin-17A.

Objectives: The aim of this interim analysis is to describe selected baseline (BL) demographics, to evaluate SEC effectiveness on disease activity and global functioning and health, and to report safety profile depending on smoking status of AS pts.

Methods: AQUILA is an ongoing, multi-center, non-interventional study including up to 2700 pts with active AS or psoriatic arthritis. Pts were observed from BL up to week (w) 52. Real-world data was assessed prospectively and analyzed as observed. Assessment of CRP and validated questionnaires were used to collect data on disease activity (Bath Ankylosing Spondylitis Disease Activity Index, BASDAI), global functioning and health (Assessment of SpondyloArthritis-Health Index, ASAS-HI) and depressive mood (Beck’s Depression Inventory version II, BDI-II). For calculation of proportion of pts who experienced (serious) adverse events (S)AEs, all AS pts were included who received at least one dose of SEC irrespective of further documentation of any study visit. This analysis focuses on the subgroups non-smoker (NS) and smoker (S).

Results: At BL, 311 AS pts were included: 42.1% (n=131) NS and 32.8% (n=102) S. Remaining subgroups were 15.1% (n=47) ex-smoker and 10.0% (n=31) of unknown smoking status. About half of AS pts in NS were male, while in S (89.6%) portion of men was more than twice as high as of women. S were slightly younger than NS (mean age: 43.9/49.0 years). During the study, CRP value decreased irrespective of smoking status with numerically higher fluctuations in S (Fig. 1A). BASDAI (NS: 5.2 at BL to 3.7 at w52, S: 5.6 at BL to 4.1 at w52) and ASAS-HI (Fig. 1B) scores numerically improved best in NS, whereas more variations were seen in S; the same was observed for BDI-II score values (NS: 11.6 at BL to 9.2 at w52, S: 13.0 at BL to 12.1 at w52).

Although no major significant differences in mean values existed between NS and S, NS showed – except in w4 – overall higher mean values in the parameters mentioned above. Regarding the occurrence of AEs/SAEs with or without suspected relationship to SEC, there was no significant difference between NS and S (Table 1).

Table 1. Overview of AEs (and SAEs) under SEC treatment depending on smoking status in AS pts

<table>
<thead>
<tr>
<th>Number of pts with</th>
<th>NS (N=140), n (%)</th>
<th>S (N=110), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>96 (67.9)</td>
<td>78 (70.9)</td>
<td>0.80</td>
</tr>
<tr>
<td>AE with suspected relationship to SEC</td>
<td>60 (42.1)</td>
<td>41 (37.3)</td>
<td>0.29</td>
</tr>
<tr>
<td>SAE</td>
<td>39 (27.9)</td>
<td>30 (27.3)</td>
<td>0.95</td>
</tr>
<tr>
<td>SAE with suspected relationship to SEC</td>
<td>15 (10.7)</td>
<td>10 (9.1)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

Conclusion: In a real-world setting, SEC improved disease activity and global functioning and health in AS pts with slight (mostly non-significant) differences between NS and S. Overall, this interim analysis shows that SEC is an effective treatment with a favorable safety profile up to 52 weeks, irrespective of the pts’ smoking status. Further progress of the AQUILA study will reveal whether this trend will continue.

REFERENCES


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FACTORS ASSOCIATED WITH PERSISTENCE OF GOLIMUMAB TREATMENT IN THE BIOBADASER REGISTRY, UP TO 7 YEARS OF FOLLOW-UP


Background: Persistence in treatment with a biological drug can be considered an indirect measure of efficacy, safety and tolerability

Objectives: We assessed the probability of persistence of golimumab treatment in patients with rheumatic diseases and the factors associated with persistence up to 7 years of follow-up.

Methods: BIOBADASER is the Spanish registry of biological drugs of the Spanish Society of Rheumatology and the Spanish Medicines Agency. A data-base analysis was done in Dec 2019 on all the patients aged 18 years or older who had initiated golimumab for rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritides (SpA). The probability of persistence was calculated with a Kaplan-Meier test. Factors related to persistence were analyzed with a Cox-regression model.

Results: There were 685 patients included (195 [28.5%] RA, 294 [42.9%] axial SpA and 196 [28.6%] PsA) in the analysis (Mean age 51.3 [12.6] years, 53.7% women). Median duration of disease at the onset of golimumab therapy was 7.6 (3.0-14.5) years. Golimumab was prescribed as first biological drug in 36.4%, as second in 31.7% and as third or further in 31.9% of the patients. Concomitant medication at golimumab initiation included methotrexate (40.0%), corticosteroids (34.2%), leflunomide (17.8%) and sulfasalazine (8.1%). The probability of persistence with golimumab treatment was 71.7% (95% CI 68.1–74.9) at year 1, 60.5% (56.5–64.2) at year 2, 55.6% (51.5–59.5) at year 3, 50.6% (46.2–54.8) at year 4, 45.1% (40.1–50.0) at year 5, 44.2% (39.0–49.3) at year 6 and 39.5% (32.8–46.2) at year 7. As the first biological agent the probability of persistence was 22% at year 1 and 60.0% at year 5. As a second biological drug persistence was 70.4% and 39.9% (year 1 and 7). Cox-regression analysis (table) showed that the probability of persistence with golimumab treatment was higher in first vs second or third biological line (Hazard Ratio[HR] for discontinuation: 1.45 for second and 3.04 for third or further vs first line), in SpA and PsA patients (HR discontinuation vs RA:0.56 and 0.49 respectively) and in patients with methotrexate (HR:0.61) and lower in those needing corticosteroids(HR:1.71) or DMARDs different to methotrexate (HR:1.98) and in patients with higher disease activity at golimumab onset (HR:1.45)

Conclusion: The probability of persistence on golimumab therapy was high and remained relatively stable up to 7 years of follow-up. A lower risk of treatment...