Figure. Change following 12 weeks of CZP treatment in clinical response and measures of objective signs of inflammation in patients with A) r-axSpA and B) nr-axSpA

Conclusion: Higher inflammatory burden as reflected by BLDD longer than 5 or 10 years were predictors associated with IHT after adjusting for inflammation marker and traditional CV risk factors. Higher ESR level may also play a role in the development of IHT in these patients.

REFERENCES:

Table 1. Multivariable analysis with time-dependent Cox proportional hazard regression for the predictors of incident hypertension stratified by baseline disease duration.

<table>
<thead>
<tr>
<th>ESR</th>
<th>Model 1</th>
<th>Model 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESR≥20</td>
<td>4.14 (0.75, 22.75) 0.102</td>
<td>3.96 (0.74, 21.32) 0.109</td>
</tr>
<tr>
<td>csDMARDs</td>
<td>1.14 (0.18, 7.37) 0.891</td>
<td>1.11 (0.10, 1.20) 0.998</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>8.20 (0.21, 3.18) 0.774</td>
<td>8.23 (0.21, 3.30) 0.758</td>
</tr>
<tr>
<td>Age</td>
<td>2.74 (0, ∞) 0.998</td>
<td>2.77 (0, ∞) 0.998</td>
</tr>
<tr>
<td>BMI</td>
<td>1.12 (1.00, 1.27) 0.060</td>
<td>1.12 (1.00, 1.27) 0.070</td>
</tr>
</tbody>
</table>

HR, Hazard ratio; BLDD: baseline disease duration; ESR: Erythrocyte Sedimentation Rate; BMI: Body mass index; y, years.

Keywords: axial spondyloarthritis, Clinical response, Prediction models, Risk factors, Treatment outcomes, vascular events.

Background: HT is the most prevalent comorbidity in axSpA (1), and is one of the strongest predictors for accelerated atherosclerosis and atherosclerotic vascular events in the general populations [2]. However, the association between time-varying inflammatory markers, disease activity and drug use and the development of incident hypertension (IHT) remain unknown.

Objectives: To elucidate the time-varying risk factors for the development of IHT in patients with axial spondyloarthritis (axSpA).

Methods: We conducted a long-term retrospective cohort study in axSpA patients who were recruited from 2001-2019 from a university clinic in Hong Kong. Patients with HT and/or anti-hypertensive drug use at baseline were excluded. They were followed until the end of 2020. The outcome was IHT, defined by a diagnosis and/or a prescription for an antihypertensive drug. Baseline and time-varying Cox regression analyses adjusting for age, sex, and body mass index (BMI), were used to assess the relationship between inflammatory burden, drug use and IHT.

Results: 413 patients [age: 34(25-43) years, male: 319 (77.2%)] were recruited. After a median follow up of 12 (6-17) years, 58 patients (14%) developed IHT (IHT-group). Among all the baseline variables, disease duration (BLDD) was the only independent predictor for IHT based on the Cox regression model. In the time-varying multivariate Cox regression analysis, ESR level as an inflammatory marker and BLDD longer than 5 or 10 years, remained as the significant independent predictors to increase risk of future IHT (Table 1a and 1b), while ESR≥20, the use of csDMARDs, sulfasalazine or paracetamol were no longer statistically significant. The Kaplan-Meier curve showed the survival probability were significant lower in groups with BLDD longer than 5 or 10 years (Figure 1).

Figure 1. The Kaplan-Meier curve for the survival probability of groups stratified by baseline disease duration over time. BLDD: baseline disease duration.

Figure 1. Kaplan-Meier curve for the survival probability of groups stratified by baseline disease duration over time. BLDD: baseline disease duration.
Keywords: Spondyloarthritis, Clinical trials, Outcome measures

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Background: Exercise can improve the symptoms of axial spondyloarthritis (axSpA) and is recommended as a cornerstone of management for axSpA [1]. Wearable devices can objectively measure physical activity and device-generated data may support development of digitally measured novel endpoints that correlate with treatment response.

Objectives: To report baseline usage and adherence with wearable technology used to assess the physical activity of people with active ankylosing spondylitis (AS) and inadequate response to biologic DMARD therapy (bDMARD-IR) in the SELECT-AXIS 2 trial, as well as evaluate the association between baseline physical activity and patient-reported measures of function and health.

Methods: Patients in the SELECT-AXIS 2 bDMARD-IR study (NCT04169373), a 1:1 randomized, double-blind, phase 3 trial of upadacitinib vs placebo [2], were required to wear a medical-grade wrist-worn actigraphy device that monitored physical activity during the 14-week, placebo-controlled portion of the study. Eligibility criteria included a diagnosis of active AS and inadequate response to bDMARDs. Wearable device adherence, defined as at least 16 hours per day usage, was evaluated through 14 weeks. Baseline physical activity measurements, including median daily steps and time spent moderate to vigorous physical activity (MVPA), were defined as those in the first week of device usage after trial entry. Median daily steps at baseline were compared by sex and day of the week (weekend vs weekday) across the entire patient cohort using the Mann–Whitney test; differences in physical activity by age were assessed with the Kruskal–Wallis test. For inclusion in all other baseline analyses, patients were required to have at least 3 out of 7 days with sufficient device use, and average physical activity was calculated over these adherent days. Finally, the comparison between baseline physical activity and functional index (BASFI) or health status (ASAS Health Index over these adherent days. Finally, the comparison between baseline physical activity and functional index (BASFI) or health status (ASAS Health Index) and health.

Of 420 total patients, physical activity data was collected from 394 participants, and 312 patients met minimal adherence criteria at baseline (first week). Through 14 weeks, adherence was demonstrated for 83.5% of study days (Figure 1A). At baseline, physical activity was higher in men than women and on weekdays than weekends; median daily steps were not significantly different between age (Figure 1B). Baseline mean BASFI and ASAS-HI in the SELECT-AXIS 2 bDMARD-IR AS trial were 6.3 and 9.3, respectively, suggesting relatively high functional limitation. Patients with higher baseline functional impairment (BASFI score >7) did not statistically differ in median daily time spent in MVPA (p=0.366) but took an average of 1690 fewer steps per day (p=0.021) than patients with BASFI scores ≤4 who met the Patient Acceptable Symptom State (PASS) (Figure 1C). Patients reporting “good” health status (4) (ASAS-HI score ≥12 to 17) spent 30.0 fewer minutes in MVPA (p=0.005) and took 2186 fewer steps per day (p=0.010) than those with “good” health status (4) (ASAS-HI scores <4, Figure 1D).

Conclusion: bDMARD-IR patients with AS in SELECT-AXIS 2 had high adherence with use of a wearable activity monitoring device over 14 weeks. Lower physical activity was generally associated with higher disability scores and poor health status at baseline. These data support the utility of wearable devices for assessing physical activity in people with AS, suggesting the possibility to use such devices to evaluate the impact of targeted therapeutics on passively collected physical activity and functional ability outcomes.

REFERENCES:

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Keywords: Spondyloarthritis


Background: Spondyloarthritis (SpA) is a family of arthritic rheumatic diseases, including axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA), that primarily affects the spine and joints. It causes inflammation of the spinal and peripheral joints that can lead to severe, chronic pain and discomfort. Diagnosing SpA has proven challenging, particularly for women who are found to be under-diagnosed in AS despite the disease affecting men and women both equally, as there are no current diagnostic criteria for axSpA [1]. Disease activity can be measured through tests such as haematology and joint count measurements.

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