Methods: The ph3 studies BE MOBILE 1 (NCT03928704; non-r-axSpA) and 2 (NCT03928743; r-axSpA) comprised a 16-wk double-blind treatment period (DBTP; subcutaneous BKZ 160 mg Q4W or PBO) followed by a 36-wk maintenance period (all pts received BKZ 160 mg Q4W) [5]. Upon entry to the ongoing BE MOVING open-label extension (OLE; [NCT04436640; cut-off 4 Jul 2022]) at Wk 52, all pts remained on BKZ 160 mg Q4W. The ph2b study BE AGILE (NCT02963506; r-axSpA) comprised a 12-wk double-blind, dose-ranging period followed by a 36-wk randomised period (BKZ 160 or 320 mg Q4W) [4]. Upon entry to the ongoing BE AGILE OLE (NCT03355573; cut-off 4 Jul 2022) at Wk 48, all pts received BKZ 160 mg Q4W. Data were pooled for all pts treated with BKZ 160 mg Q4W in the ph2b/3 trials listed above. Data were pooled separately for pts randomised to BKZ or PBO in the DBTP of BE MOBILE 1 and 2. Uveitis treatment-emergent adverse events (TEAEs) were identified using the preferred terms "autoimmune uveitis", "iridocyclitis", "iritis", and "uveitis", and were reported as both incidence and exposure adjusted incidence rates (EAIRs) per 100 pt years (PY) for all pts who received ≥1 BKZ dose.

Results: Baseline characteristics were reflective of a pt population with moderate-to-severe axSpA **(Table 1)**. In the DBTP of BE MOBILE 1 and 2, uveitis TEAEs occurred in 11/237 (4.6%; EAIR/100 PY [95% CI]: 15.4 [7.7, 27.5]) and 2/349 (0.6%; 1.8 [0.2, 6.7]) of pts randomised to PBO and BKZ (% difference [95% CI]: 4.07 [1.71, 7.60]), respectively **(Figure 1)**. In the 45 PBO-randomised (19.0%) and 52 BKZ-randomised (14.9%) pts with history of uveitis, uveitis TEAEs occurred in 20.0% (EAIR/100 PY [95% CI]: 70.4 [32.2, 133.7]) and 1.9% (6.2 [0.2, 34.8]) of pts, respectively. In the pooled ph2b/3 trial data, total BKZ exposure was 2,034.4 PY (N=848), 130 (15.3%) pts had history of uveitis. Uveitis TEAEs occurred in 25 (2.9%; EAIR/100 PY [95% CI]: 1.2 [0.8, 1.8]) and 14 (10.8%; 4.6 [2.5, 7.7]) pts overall and with history of uveitis, respectively **(Figure 1)**. All uveitis TEAEs were mild/moderate, one event led to discontinuation.

Conclusion: The incidence rate of uveitis TEAEs was lower to Wk 16 in axSpA pts randomised to BKZ 160 mg Q4W vs PBO. In the largest pool of ph2b/3 data available at the time of this report, the incidence rate of uveitis with BKZ 160 mg Q4W remained low at 1.2/100 PY.

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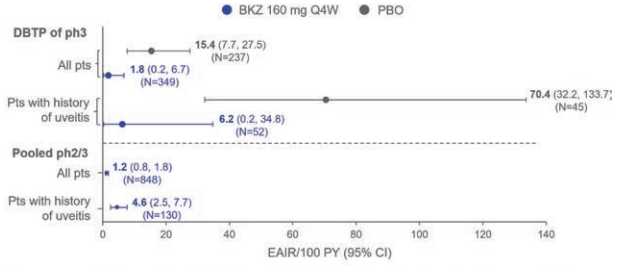
Table 1. Baseline characteristics

	Pooled ph3		Pooled ph2b/3
	PBO (N=237)	BKZ 160 mg Q4W (N=349)	BKZ 160 mg Q4W (N=848)
Age (years), mean ± SD	38.8 ± 12.1	40.0 ± 11.8	40.3 ± 11.9
Male, n (%)	145 (61.2)	233 (66.8)	606 (71.5)
HLA-B27 positive, n (%)	187 (78.9)	294 (84.2)	717 (84.6)[a]
Caucasian, n (%)	200 (84.4)	286 (81.9)	746 (88.0)
r-axSpA, n (%)	111 (46.8)	221 (63.3)	604 (71.2)
Time since first axSpA symptoms (years), mean ± SD	10.3 ± 8.9	12.4 ± 10.5	12.4 ± 9.9
History of uveitis, n (%)	45 (19.0)	52 (14.9)	130 (15.3)
Baseline concomitant synthetic DMARDs, n (%)	51 (21.5)	77 (22.1)	197 (23.2)

[a]n=6 missing.

Figure. Pooled incidence of uveitis TEAEs (EAIR/100 PY [95% CI]) stratified by history of uveitis in pts randomised to BKZ 160 mg Q4W or PBO in the DBTP (Weeks 0 –16) of the ph3 trials BE MOBILE 1 and 2, and all pts treated with BKZ 160 mg Q4W in ph2b/3 trials.



Abbreviations: axSpA: axial spondyloarthritis; BKZ: bimekizumab; CI: confidence interval; DBTP: double-blind treatment period; DMARD: disease-modifying antirheumatic drug; EAIR: exposure adjusted incidence rate; HLA-B27: human leukocyte antigen B27; PBO: placebo; ph: phase; pts: patients; PY: patient years; Q4W: every 4 weeks; r-axSpA: radiographic axSpA; SD: standard deviation; TEAE: treatment-emergent adverse event.

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POS0669

CROSS-SECTIONAL ANALYSIS OF CARDIOVASCULAR DISEASE AND RISK FACTORS IN PATIENTS WITH SPONDYLOARTHRITIS: A REAL-LIFE EVIDENCE FROM BIOSTAR NATIONWIDE REGISTRY

Keywords: Spondyloarthritis

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Background: Association between spondyloarthritis and cardiovascular (CV) diseases is a complex issue with variable outcomes.

Objectives: This study aimed to assess the prevalence rates of CV diseases and to analyze the impact of CV risk factors on CV disease in patients with spondyloarthritis.

Methods: A multi-center cross-sectional study using BioSTAR (Biological and Targeted Synthetic Disease-Modifying Antirheumatic Drugs Registry) database was performed on patients with spondyloarthritis. Socio-demographic, laboratory and clinical, data were collected. Patients with and without major adverse

cardiovascular events (MACE) were grouped as Group 1 and Group 2.The primary outcome was the prevalence rates of CV disease and CV risk factors in the overall group. The secondary outcome was the difference in socio-demographic and clinical characteristics between the groups and predictive risk factors for CV disease.

Results: There were 1457 patients with a mean age of 45.7±10.9 years. The prevalence rate for CV disease was 3% (n=44). The distribution of these diseases was coronary artery disease (n=42), congestive heart failure (n=4), peripheral vascular disorders (n=6), and cerebrovascular events (n=4). Patients in Group 1 were significantly older than those in Group 2 (p<0.001). There were significantly more patients with hypertension, diabetes mellitus, chronic renal failure, dyslipidemia, and malignancy in Group 1 than in Group 2 (p<0.05). Smoking (36.7%), obesity (24.4%), and hypertension (13.8%) were the most prevalent traditional CV risk factors. Hypertension (HR=4.994, 95% CI:1.966-12.683, p=0.001) and dyslipidemia (HR=1.960, 95% CI:1.155-6.676, p=0.024) were the independent predictors for CV disease.

Conclusion: The prevalence rate of CV disease was 3.0% in patients with spondyloarthritis. Hypertension and dyslipidemia were independent CV risk factors for CV disease in patients with spondyloarthritis.

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Table 1. Socio-demographic and clinical characteristics of the study groups.

		Overall (n=1457)	Group 1 (n=44)	Group 2 (n=1413)	p
Age (year) †		45 (18-83)	54 (41-83)	44 (18-83)	<0.001
Age group ‡	≥40 years	1021 (70.1)	44 (100.00)	977 (69.1)	<0.001
	<40 years	436 (29.9)	0 (0)	436 (30.9)	
Comorbidities ‡					
	Hypertension	201 (13.8)	27 (61.4)	174 (12.7)	<0.001
	Diabetes mellitus	105 (7.2)	10 (22.7)	95 (6.9)	0.001
	Chronic renal failure	24 (1.6)	5 (11.6)	19 (1.4)	0.001
	Dyslipidemia	61 (4.2)	15 (48.4)	46 (6.9)	<0.001
	COPD	46 (3.2)	3 (6.8)	43 (3.1)	0.160
	Malignancy	7 (0.5)	2 (4.5)	5 (0.4)	0.018
	Valvular heart disease	10 (0.7)	1 (2.3)	9 (0.6)	0.265

Table 2. Univariate and multivariate analysis for MACE during the duration of the diseases.

			Univariate	Multivariate	
Parameter	Reference	Risk factor	p	HR (95% CI)	p
Age			0.007	1.001 (0.956-1.049)	0.956
Smoking	Non-/ex-smoker	Smoker	0.128	0.598 (0.223-1.601)	0.306
Alcohol	Non-/ex-consumer	Consumer	0.158	0.703 (0.231-2.142)	0.535
Hypertension	Absent	Present	<0.001	4.994 (1.966-12.683)	0.001
Diabetes mellitus	Absent	Present	0.297	0.629 (0.206-1.920)	0.416
Chronic renal failure	Absent	Present	0.013	1.241 (0.182-8.445)	0.826
Dyslipidemia	Absent	Present	<0.001	2.960 (1.155-6.776)	0.024
Chronic obstructive pulmonary disease	Absent	Present	0.330	0.809 (0.131-4.982)	0.819
Malignancy	Absent	Present	0.003	2.293 (0.131-40.212)	0.570
Phenotypes of SpA	Diagnoses other than r- axSpA	r- axSpA	0.365	0.788 (0.309-1.930)	0.581
BASDAI group	Non-high risk	High-risk	0.404	0.750 (0.325-1.727)	0.498
ASDAS-CRP group	Non-high risk	High-risk	0.063	2.158 (0.834-5.587)	0.113

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Disclosure of Interests: None Declared.
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POS0670

DIAGNOSTIC DELAY IS ASSOCIATED WITH WORSE OUTCOMES IN TERMS OF STRUCTURAL DAMAGE IN PATIENTS WITH RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS. RESULTS FROM REGISPONSER-AS

Keywords: Descriptive Studies, Outcome measures, Spondyloarthritis

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Background: Diagnostic delay in axial Spondyloarthritis (axSpA) is longer than in many other rheumatic diseases. It has been demonstrated to be associated with socioeconomic factors, disease presentation [1], HLA-B27 negativity, female sex, psoriasis and younger age at onset [2]. Prolonged delay is associated with poorer long-term outcomes, including functional impairment and quality of life.

Objectives: To evaluate whether diagnostic delay in patients with radiographic axSpA (r-axSpA) is associated with poorer short-term outcomes after two years of follow-up.

Methods: Observational, longitudinal and prospective study including patients from the REGISPONSER-AS study (Spondyloarthritis Registry of the Spanish Rheumatology) with a diagnosis of r-axSpA according to the modified NY criteria. At baseline, the patients were divided into two groups according to the median of diagnosis delay (<5 years, ≥5 years). Binary logistic regression models adjusted for disease duration were constructed to evaluate the association between the diagnosis delay and disease outcomes at two years. The retention rate of the first anti-TNF treatment across the groups was evaluated using a log-rank test.

Results: A total of 729 patients were included. Outcomes at two years according to diagnosis delay are presented in the Table 1. Characteristics related with structural chronic damage (BASRI, occiput wall distance), inflammatory bowel disease (IBD), dactylitis, SF-12 mental component and inability to work were associated with longer diagnosis delay. No differences were found in the retention rate of the first anti-TNF antibody between the groups.

Conclusion: Diagnostic delay is associated with poorer short-term outcomes in terms of structural damage, prevalence of IBD, dactylitis, SF-12 mental component and inability to work in patients with r-axSpA.

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Table 1. Outcomes at 2 years adjusted by disease duration

	Diagnosis delay <5 years (N = 364)	Diagnosis delay 5 or more years (N = 365)	OR (95% CI)	p-value*
Age (years) at diagnosis	30.95 (10.53)	39.42 (11.59)	1.09 (1.07 – 1.1)	**<0.001**
Sex (male)	274 (75.3)	279 (75.8)	1.28 (0.89 – 1.86)	0.19
HLA-B27 positive	282 (81.3)	292 (81.6)	1.24 (0.81 – 1.88)	0.321
Psoriasis	41 (11.5)	39 (11)	1.02 (0.61 – 1.73)	0.926
IBD	19 (5.4)	27 (7.6)	0.41 (0.21 – 0.78)	**0.007**
Uveitis	82 (23.2)	83 (23.2)	1.28 (0.87 – 1.88)	0.215
CRP (mg/dL)	9.11 (14.62)	9.43 (11.78)	0.99 (0.99 – 1.01)	0.796
ASDAS-CRP, mean (SD)	2.49 (0.99)	2.67 (1.04)	1.06 (0.9 – 1.25)	0.47
BASDAI, mean (SD)	3.58 (2.15)	4.07 (2.36)	1.06 (0.99 – 1.14)	0.109
BASFI, mean (SD)	36.63 (27.55)	44.38 (27.1)	1 (0.99 – 1.01)	0.832
VAS (cm)	4.04 (2.55)	4.4 (2.61)	1.03 (0.97 – 1.1)	0.333
SF - 12 physical component	36.76 (9.45)	34.86 (9.97)	0.99 (0.97 – 1)	0.137
SF - 12 mental component	49.31 (9.85)	48.46 (11.3)	0.98 (0.97 – 0.99)	**0.04**
Radiographic sacroiliitis	347 (96.7)	356 (97.5)	1.35 (0.54 – 3.4)	0.523
Spine BASRI	6.55 (3.34)	7.33 (3.03)	0.94 (0.88 – 0.99)	**0.042**
Total BASRI	7.32 (3.97)	8.28 (3.65)	0.94 (0.89 – 0.99)	**0.02**
Magnetic resonance	11 (3)	11 (3)	1.07 (0.39 – 2.93)	0.9
Enthesitis	133 (38.4)	148 (41.2)	1.03 (0.67 – 1.58)	0.886
Dactilytis	39 (11.3)	18 (5.1)	0.47 (0.25 – 0.89)	**0.02**
Hip arthroplasty	19 (5.5)	18 (5.1)	4.02 (1.86 – 8.69)	**< 0.001**
Schober (cm)	3.23 (1.72)	2.89 (1.62)	1.09 (0.98 – 1.2)	0.099
Chest expansion (cm)	4.24 (2.1)	3.7 (2)	0.99 (0.91 – 1.07)	0.796
Distance to ground (cm)	18.02 (14.26)	21.6 (13.95)	1 (0.99 – 1.01)	0.687
Occiput wall distance (cm)	4.13 (6.43)	5.36 (6.64)	0.97 (0.94 – 0.99)	**0.015**
Lumbar lateral flexion (cm)	20.96 (18.01)	19.06 (18.19)	0.99 (0.99 – 1)	0.778
Inability to work				
-Transitory	14 (4.1)	13 (3.8)	1.5 (1.07 – 2.27)	**0.02**
-Permanent	90 (26.5)	110 (31.9)		

* Binary logistic regression

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